

**EXHIBITS 1-14
TO THE DECLARATION
OF JEFFREY B.
COOPERSMITH IN
SUPPORT OF DEFENDANT
RAMESH BALWANI'S
OMNIBUS MOTIONS IN
LIMINE**

EXHIBIT 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 6
)
ELIZABETH A. HOLMES,) SEPTEMBER 14, 2021
)
DEFENDANT.) PAGES 660 - 854
_____)

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

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CERTIFICATE NUMBER 8074
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CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

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WILLIAMS & CONNOLLY
BY: TIMIKA ADAMS-SHERMAN, PARALEGAL

TBC
BY: BRIAN BENNETT, TECHNICIAN

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ERIKA CHEUNG

DIRECT EXAM BY MR. BOSTIC P. 789

12:41PM 1 LAB ASSOCIATE, AND THEN WAS INTEGRATED INTO THE CLINICAL LAB AS
12:41PM 2 A LAB ASSOCIATE WHERE THE CLINICAL LAB IS EFFECTIVELY WHERE THE
12:41PM 3 PATIENT PROCESSING OCCURRED OR OCCURS AT THERANOS.

12:41PM 4 Q. WHAT WERE YOUR DATES OF EMPLOYMENT AT THERANOS?

12:41PM 5 A. I WORKED AT THERANOS OCTOBER 2013 TO ABOUT APRIL OF 2014.

12:41PM 6 Q. OKAY. APPROXIMATELY SIX MONTHS GIVE OR TAKE?

12:41PM 7 A. YES.

12:41PM 8 Q. HOW DID YOUR EMPLOYMENT AT THERANOS END? WERE YOU
12:41PM 9 TERMINATED? LAID OFF? DID YOU RESIGN?

12:42PM 10 A. I RESIGNED.

12:42PM 11 Q. AND IN GENERAL TERMS, WHAT WAS THE REASON FOR RESIGNING
12:42PM 12 FROM YOUR JOB AT THERANOS?

12:42PM 13 A. I LEFT THERANOS BECAUSE I WAS UNCOMFORTABLE PROCESSING
12:42PM 14 PATIENT SAMPLES AND I DID NOT FEEL THAT THE TECHNOLOGY THAT WE
12:42PM 15 WERE USING IN ORDER TO PROCESS PATIENT SAMPLES WAS ADEQUATE
12:42PM 16 ENOUGH TO BE ENGAGING IN THAT BEHAVIOR OF PROCESSING PATIENT
12:42PM 17 SAMPLES.

12:42PM 18 AFTER LOTS OF CONVERSATIONS WITH VARIOUS EXECUTIVES AND
12:42PM 19 PEOPLE WITHIN THE ORGANIZATION, I HAD MADE THE DECISION TO
12:42PM 20 LEAVE THE ORGANIZATION.

12:42PM 21 Q. OKAY. LET'S GO BACK IN TIME A LITTLE BIT.

12:42PM 22 CAN YOU SUMMARIZE YOUR EDUCATION FOR ME BEGINNING POST
12:42PM 23 HIGH SCHOOL?

12:42PM 24 A. POST HIGH SCHOOL EDUCATION, I GRADUATED FROM
12:42PM 25 U.C. BERKELEY, UNIVERSITY OF CALIFORNIA BERKELEY, AND I

12:42PM 1 RECEIVED A DEGREE IN MOLECULAR AND CELLULAR BIOLOGY AND A

12:43PM 2 BACHELOR'S IN LINGUISTICS, SO A DUAL DEGREE.

12:43PM 3 Q. WAS THERANOS YOUR FIRST EMPLOYMENT OUT OF COLLEGE?

12:43PM 4 A. YES.

12:43PM 5 Q. AND HOW DID YOU FIRST HEAR ABOUT THE COMPANY THERANOS?

12:43PM 6 A. I FIRST HEARD ABOUT THERANOS AT A STUDENT CAREER FAIR AT

12:43PM 7 THE U.C. BERKELEY CAMPUS, AND ESSENTIALLY THEY'RE BOOTHS SET UP

12:43PM 8 WITH DIFFERENT COMPANIES, AND THERANOS HAD PROBABLY THE MOST

12:43PM 9 POPULAR BOOTH. IT HAD KIND OF A LINE OUT THE DOOR OF PEOPLE

12:43PM 10 WAITING TO TALK TO THE RECRUITER THERE, AND SO I WAITED IN LINE

12:43PM 11 TO TALK TO ONE OF THE RECRUITERS TO BE A PART OF THE COMPANY.

12:43PM 12 Q. AND AT THAT TIME DID YOU KNOW MUCH ABOUT THE BUSINESS OF

12:43PM 13 THE COMPANY, WHAT IT WAS DOING?

12:43PM 14 A. NO.

12:43PM 15 Q. DID YOU THEN GO THROUGH THE JOB INTERVIEW PROCESS FOR A

12:43PM 16 POSITION AT THERANOS?

12:43PM 17 A. YES. SO ESSENTIALLY AFTER WAITING IN LINE, I HANDED OVER

12:43PM 18 MY RESUME TO THE RECRUITER, AND SHE SAID WE'RE HIRING A WHOLE

12:44PM 19 BUNCH OF PEOPLE FOR MANY DIFFERENT POSITIONS, LET ME SUBMIT

12:44PM 20 YOUR RESUME AND GIVE YOU A CALL TO SEE WHAT OPENING POSITIONS

12:44PM 21 YOU'LL HAVE.

12:44PM 22 SO AFTER I SUBMITTED MY RESUME I HAD GOTTEN A CALL BACK

12:44PM 23 AND THEY HAD TOLD ME THAT I HAD A PHONE INTERVIEW WITH THE

12:44PM 24 COMPANY FOR A POTENTIAL POSITION, AN ENTRY LEVEL POSITION.

12:44PM 25 AND THEN I PROCEEDED TO GO THROUGH THEIR INTERVIEW PROCESS

12:54PM 1

A. YES.

12:54PM 2

Q. HOW ABOUT THE DEVICES USED BY THE COMPANY. AS PART OF

12:54PM 3

YOUR ROLE DID YOU BECOME FAMILIAR WITH THE KINDS OF ANALYZERS

12:54PM 4

THAT THERANOS WAS USING TO TEST PATIENT BLOOD SAMPLES?

12:54PM 5

A. YES.

12:54PM 6

Q. AND DID THERANOS MANUFACTURE SOME BLOOD ANALYZERS?

12:54PM 7

A. YES, THEY DID.

12:54PM 8

Q. WHAT WERE THOSE?

12:55PM 9

A. THE DEVICES THAT THERANOS MANUFACTURED WERE THE EDISON,

12:55PM 10

THE EDISON DEVICES.

12:55PM 11

Q. AND WERE THERE DIFFERENT VERSIONS OF THE EDISON DEVICES?

12:55PM 12

A. YES. SO THERE WAS THE EDISON 3.0'S AND THE EDISON 3.5'S.

12:55PM 13

Q. AND WERE THOSE TWO DIFFERENT VERSIONS OF THE SAME BASIC

12:55PM 14

DEVICE?

12:55PM 15

A. YES.

12:55PM 16

Q. AND THERE'S A BINDER ON THE DESK IN FRONT OF YOU. IF I

12:55PM 17

COULD ASK YOU TO OPEN THAT AND TURN TO A TAB LABELLED

12:55PM 18

EXHIBIT 5388.

12:55PM 19

LET ME KNOW WHEN YOU'RE THERE.

12:55PM 20

A. IS IT IN THE FRONT OF 5388 OR THE BACK?

12:55PM 21

Q. IT SHOULD BE IN THE BACK. I THINK IT'S THE SECOND TO THE

12:55PM 22

LAST TAB IN THE BINDER.

12:55PM 23

A. YES.

12:55PM 24

Q. AND YOU SHOULD BE LOOKING AT AN IMAGE.

12:55PM 25

A. YES.

01:02PM 1 THERANOS WAS OFFERING AT THE TIME?

01:02PM 2 A. YES.

01:02PM 3 Q. I THINK YOU JUST ANSWERED THIS QUESTION AS WELL, BUT JUST
01:02PM 4 TO BE CLEAR, DURING YOUR TIME AT THERANOS, DID THERANOS RUN
01:02PM 5 PATIENT BLOOD TESTS ONLY ON THE EDISON, THE THERANOS BUILT
01:03PM 6 ANALYZER?

01:03PM 7 A. NO.

01:03PM 8 Q. DID IT USE OTHER TYPES OF DEVICES FOR PATIENT BLOOD SAMPLE
01:03PM 9 TESTING?

01:03PM 10 A. YES.

01:03PM 11 Q. WHAT WERE THE OTHER TYPES OF DEVICES THAT THERANOS USED
01:03PM 12 FOR PATIENT SAMPLE TESTING?

01:03PM 13 A. SO THERANOS HAD UTILIZED OTHER FDA APPROVED MACHINES THAT
01:03PM 14 THEY HAD MODIFIED IN ORDER TO BE ABLE TO HANDLE THE SMALL BLOOD
01:03PM 15 SAMPLES THAT WE HAD.

01:03PM 16 SO ONE OF THEM FOR CHEMISTRY SAMPLES WAS CALLED THE
01:03PM 17 SIEMENS ADVIA, AND THAT'S A NORMAL FDA APPROVED MACHINE THAT
01:03PM 18 YOU WOULD FIND IN HOSPITALS AND YOU CAN BUY OFF THE SHELF.

01:03PM 19 ANOTHER ONE FOR ALL OF THE HEMATOLOGY SAMPLES WE WOULD USE
01:03PM 20 A MACHINE CALLED THE BSD FORTESSA, IT'S A FLOW CYTOMETER, AND
01:03PM 21 THAT WAS ANOTHER DEVICE THAT WE USED IN ORDER TO RUN ALL OF THE
01:04PM 22 CYTOLOGY OR HEMATOLOGY SAMPLES.

01:04PM 23 Q. THE DEVICES THAT YOU'RE TALKING ABOUT RIGHT NOW, WERE
01:04PM 24 THOSE DEVICES MANUFACTURED OR DEVELOPED BY THERANOS?

01:04PM 25 A. NO.

01:04PM 1
01:04PM 2
01:04PM 3
01:04PM 4
01:04PM 5
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01:05PM 21
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01:05PM 24
01:05PM 25

Q. WERE THEY INSTEAD DEVELOPED AND SOLD BY THIRD PARTY COMPANIES?

A. YES.

Q. IN THE BINDER IN FRONT OF YOU, CAN I ASK YOU TO TURN TO EXHIBIT 5389. THAT SHOULD BE JUST THE NEXT ONE IN ORDER. YOU SHOULD SEE AN IMAGE THERE.

A. YES.

Q. AND DO YOU RECOGNIZE WHAT IS DEPICTED IN THAT IMAGE?

A. YES. THIS IS THE SIEMENS ADVIA.

Q. IS THE IMAGE MARKED AS EXHIBIT 5389 A TRUE AND CORRECT DEPICTION OF THAT DEVICE BASED ON YOUR EXPERIENCE?

A. YES.

MR. BOSTIC: YOUR HONOR, THE GOVERNMENT WOULD MOVE TO ADMIT EXHIBIT 5389 AT THIS TIME.

MR. WADE: NO OBJECTION, YOUR HONOR.

THE COURT: IT'S ADMITTED, AND IT MAY BE PUBLISHED.

(GOVERNMENT'S EXHIBIT 5389 WAS RECEIVED IN EVIDENCE.)

BY MR. BOSTIC:

Q. MS. CHEUNG, ARE WE NOW LOOKING AT THE SIEMENS ADVIA ANALYZER?

A. YES.

Q. AND WHAT DID THIS LOOK LIKE IN PERSON?

A. THIS DEVICE, IT'S LARGER. IT'S ABOUT THE SIZE OF -- IT WOULD BE LIKE THE SIZE OF A WASHER AND DRYER IF YOU PUT IT TOGETHER, SO IT WAS QUITE LARGE. YOU COULD FIT PROBABLY TWO TO

01:13PM 1 SIGNIFICANTLY MORE TYPES OF ASSAYS THAN THE THERANOS-BUILT
01:13PM 2 EDISON?

01:13PM 3 A. YES.

01:13PM 4 Q. AND WERE THERE SOME -- LET ME FIRST ASK, THE TEST THAT
01:13PM 5 COULD NOT BE RUN ON THE EDISON, FOR EXAMPLE, YOU LISTED SEVERAL
01:13PM 6 OF THE COMMON PANELS IN THAT LIST; IS THAT RIGHT?

01:13PM 7 A. YES.

01:13PM 8 Q. AND ARE THEY CALLED COMMON PANELS BECAUSE THEY'RE COMMON
01:13PM 9 AND FREQUENTLY ORDERED?

01:13PM 10 A. YES.

01:13PM 11 Q. LOOKING AT THE TEST MENU, WERE THERE SOME THAT COULD NOT
01:13PM 12 BE RUN ON THE EDISON OR THE THIRD PARTY MODIFIED?

01:13PM 13 A. YES.

01:13PM 14 Q. AND WHAT DID THERANOS DO TO RUN THOSE TESTS?

01:14PM 15 A. SO THERANOS ARE SOME OF THESE FDA APPROVED MACHINES, SORT
01:14PM 16 OF PREDICATED MACHINES IN AN UPSTAIRS LABORATORY WHERE THEY
01:14PM 17 COULD RUN SOME VENOUS SAMPLES, SO THEY WOULD COLLECT A VENOUS
01:14PM 18 TUBE AND RUN THEM IN THE UPSTAIRS LABORATORY.

01:14PM 19 AND IF IT WAS SOMETHING THAT WE DIDN'T POSSESS IN HOUSE IN
01:14PM 20 ORDER TO PROCESS, IT WOULD BE SENT TO AN ORGANIZATION CALLED
01:14PM 21 ARUP, IT'S A-R-U-P, LABORATORIES, ALL CAPS FOR A-R-U-P, IN
01:14PM 22 ORDER TO DO THE ONES THAT WE DIDN'T HAVE IN-HOUSE CAPABILITIES
01:14PM 23 TO RUN.

01:14PM 24 Q. SO NOW WE'RE TALKING ABOUT DEVICES THAT WERE NOT INVENTED
01:14PM 25 OR MANUFACTURED BY THERANOS; IS THAT CORRECT?

01:14PM 1

A. YES.

01:14PM 2

Q. AND DEVICES THAT HAVE NOT BEEN CHANGED OR ALTERED BY

01:14PM 3

THERANOS IN ANY WAY?

01:14PM 4

A. YES.

01:14PM 5

Q. ARE THESE DEVICES THAT ANY BLOOD LAB TO YOUR KNOWLEDGE

01:14PM 6

COULD PURCHASE AND OPERATE THE SAME WAY THAT THERANOS DID?

01:15PM 7

A. YES.

01:15PM 8

Q. AM I UNDERSTANDING CORRECTLY THAT EVEN THOSE CATEGORIES

01:15PM 9

THAT WE'VE TALKED ABOUT, THE THERANOS'S BUILT EDISON, THE

01:15PM 10

MODIFIED THIRD PARTY DEVICES, AND THE UNMODIFIED STORE BOUGHT

01:15PM 11

THIRD PARTY DEVICES, THOSE THREE CATEGORIES WERE STILL NOT

01:15PM 12

SUFFICIENT FOR THERANOS TO BE ABLE TO CONDUCT ALL OF THE

01:15PM 13

TESTING THAT IT OFFERED?

01:15PM 14

A. YES.

01:15PM 15

Q. AND HOW DID IT HANDLE THE KINDS OF TESTS THAT IT COULD NOT

01:15PM 16

PERFORM IN HOUSE?

01:15PM 17

A. IT WOULD SEND THEM OFF TO A THIRD PARTY ESSENTIALLY TO RUN

01:15PM 18

THOSE SAMPLES.

01:15PM 19

Q. AND THAT WAS AN INDEPENDENT THIRD PARTY NOT AFFILIATED

01:15PM 20

WITH THERANOS?

01:15PM 21

A. YES.

01:15PM 22

Q. I'D LIKE TO TALK A LITTLE BIT ABOUT YOUR WORK IN THE

01:15PM 23

RESEARCH AND DEVELOPMENT LAB?

01:15PM 24

A. OKAY.

01:15PM 25

Q. WHEN YOU WERE WORKING IN R&D, DID YOU COME TO UNDERSTAND

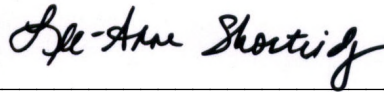
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: SEPTEMBER 14, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

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PLAINTIFF,) SAN JOSE, CALIFORNIA
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ERIKA CHEUNG

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10:18AM 1 THE PROBLEMS WITH THE QC FAILING, BUT IT CAUSED A WHOLE WEALTH
10:19AM 2 OR OTHER OPERATIONAL ISSUES WITHIN THERANOS, TOO.

10:19AM 3 Q. I UNDERSTOOD FROM YOUR TESTIMONY THAT MANY DIFFERENT
10:19AM 4 POSSIBLE REASONS FOR THE QC FAILURES WERE DISCUSSED.

10:19AM 5 A. YES.

10:19AM 6 Q. IN THOSE DISCUSSIONS, DID YOU FEEL LIKE THERE WAS A
10:19AM 7 POSSIBLE EXPLANATION THAT WAS IGNORED OR NOT GIVEN ENOUGH
10:19AM 8 ATTENTION?

10:19AM 9 A. WELL, I MEAN, I THINK THE MOST OBVIOUS ONE, THE FACT THAT
10:19AM 10 THEY WERE HAPPENING SO FREQUENTLY IS JUST THE TESTING SYSTEM,
10:19AM 11 THE EDISON DEVICES DIDN'T WORK. THEY WEREN'T WORKING ON THE
10:19AM 12 ASSAYS AND IN COMBINATION WITH THE DEVICE, IN COMBINATION WITH
10:19AM 13 THE CARTRIDGES JUST WASN'T ADEQUATE ENOUGH AND WASN'T
10:19AM 14 PERFORMING RELIABLY OR EFFECTIVELY TO THE STANDARDS THAT YOU
10:19AM 15 WOULD TYPICALLY SEE FOR ANY OTHER TYPE OF MEDICAL DIAGNOSTIC,
10:19AM 16 AND THAT WAS KIND OF THE OBVIOUS BUT -- OBVIOUS EXPLANATION OF
10:19AM 17 WHY THE QC'S WERE FAILING.

10:19AM 18 Q. DID YOU FEEL LIKE, IN THAT DISCUSSION WITH DANIEL YOUNG,
10:20AM 19 NOT ENOUGH ATTENTION WAS PAID TO THAT POSSIBILITY?

10:20AM 20 A. YES.

10:20AM 21 Q. I'D DIRECT YOU TO EXHIBIT 1431 IN THE BINDER IN FRONT OF
10:20AM 22 YOU. ONCE YOU'RE THERE, TAKE A LOOK AT IT AND LET ME KNOW IF
10:20AM 23 YOU RECOGNIZE THAT DOCUMENT.

10:20AM 24 A. YES.

10:20AM 25 Q. WHAT IS EXHIBIT 1431?

11:34AM 1 ANALYZERS?

11:34AM 2 A. YES.

11:34AM 3 Q. WOULD THAT MEAN THAT PERCENT RECOVERY VALUES OF
11:34AM 4 100 PERCENT OR CLOSE TO 100 PERCENT WOULD BE FAVORABLE RESULTS?

11:34AM 5 A. YES.

11:34AM 6 Q. IS THAT GENERALLY WHAT YOU SAW IN THIS DATA? WERE THE
11:34AM 7 RESULTS FAVORABLE IN YOUR VIEW?

11:34AM 8 A. NO.

11:34AM 9 Q. CAN YOU WALK US THROUGH THAT. HOW CAN WE TELL THAT FROM
11:34AM 10 THIS INFORMATION?

11:34AM 11 A. SO IF WE LOOK AT VITAMIN D, VITAMIN D YOU SEE THAT THE
11:34AM 12 THERANOS VALUE IS MUCH HIGHER THAN WHAT THE PREDICATE METHOD
11:34AM 13 IS.

11:34AM 14 SO SOMETIMES YOU SEE THAT THE VITAMIN D LEVEL IS THREE
11:35AM 15 TIMES THE VALUE OF WHAT YOU WOULD GET FOR THE PREDICATE METHOD.

11:35AM 16 THE REASON THIS IS IMPORTANT IS BECAUSE THIS COULD BE TWO
11:35AM 17 VERY DIFFERENT DIAGNOSES OF A PARTICULAR PATIENT.

11:35AM 18 SO, FOR EXAMPLE, FOR NY E09 ON COLUMN F YOU SEE THERE'S
11:35AM 19 373 PERCENT RECOVERY. SO THIS MEANS THAT THE VALUE IS THREE
11:35AM 20 TIMES HIGHER, MORE THAN THREE TIMES HIGHER THAN YOU SAW IN THE
11:35AM 21 PREDICATE METHOD.

11:35AM 22 SO IF THIS IS A PATIENT, THIS COULD BE THE DIFFERENCE
11:35AM 23 BETWEEN HAVING A DEFICIENCY VERSUS BEING IN THE NORMAL RANGE.

11:35AM 24 I'M NOT SURE WHAT THE CLINICAL RANGES ARE FOR THIS BUT IT'S
11:35AM 25 DIFFERENT DIAGNOSES.

11:57AM 1 WASN'T USED DURING THAT SHIFT FOR PATIENT TESTING; IS THAT
11:57AM 2 CORRECT?

11:57AM 3 A. CORRECT.

11:57AM 4 Q. DID THAT PRACTICE ADDRESS YOUR CONCERNS ABOUT THE QC
11:57AM 5 NUMBERS AT THERANOS?

11:57AM 6 A. NO.

11:57AM 7 Q. WHY NOT?

11:57AM 8 A. BECAUSE OF THE FREQUENCY OF THEM, RIGHT? IT SHOULDN'T BE
11:57AM 9 THE CASE THAT A QUARTER OF THE TIME YOU'RE HAVING THESE QUALITY
11:58AM 10 CONTROL SAMPLES FAILING. THAT'S EXTRAORDINARILY HIGH FOR ANY
11:58AM 11 LAB TEST TO HAPPEN.

11:58AM 12 AND IN ADDITION TO THAT, IT SHOWS THAT THERE'S JUST --
11:58AM 13 IT'S CONCERNING BECAUSE, AGAIN, WITH THE QUALITY CONTROLS I
11:58AM 14 HAVE THE KNOWN CONCENTRATION, BUT THE MOMENT I GO TO THE
11:58AM 15 PATIENTS, IF I FORECAST OUT WHAT THOSE RESULTS ARE, THAT ONE
11:58AM 16 OUT OF FOUR TIMES I MIGHT GIVE A PATIENT THE WRONG RESULT.

11:58AM 17 AND AT THERANOS, YOU KNOW, AT FIRST WE WERE RUNNING LIKE
11:58AM 18 10 PATIENTS, BUT IT WOULD BE THE EXPECTATION THAT WE WOULD BE
11:58AM 19 2,000 PATIENTS A DAY. LIKE, THAT'S A LOT OF PEOPLE TO
11:58AM 20 BASICALLY BE EXPECTING BASED ON THIS INFORMATION THAT A QUARTER
11:58AM 21 OF THEM WOULDN'T GET THE RIGHT RESULTS FOR THEIR HEALTH STATUS.

11:58AM 22 SO IT WAS IMMENSELY CONCERNING TO SEE THIS DEGREE OF
11:59AM 23 FAILURES BECAUSE IT'S JUST NOT TYPICAL FOR A NORMAL LAB.

11:59AM 24 LIKE, IN A NORMAL LAB YOU WOULD WANT TO SEE LESS THAN
11:59AM 25 1 PERCENT, RIGHT? THESE ARE VERY SMALL -- 1 PERCENT OF

01:49PM 1 A. YES.

01:49PM 2 Q. DID YOU KNOW WHAT THEY WERE?

01:49PM 3 A. NO.

01:49PM 4 Q. WHAT LEVEL -- AND I UNDERSTAND THESE QUALIFICATIONS ARE

01:49PM 5 LARGELY BASED UPON EXPERIENCE AND AGE AND THINGS LIKE THAT, BUT

01:49PM 6 WHAT LEVEL OF POSITION WERE YOU QUALIFIED FOR UNDER THE

01:49PM 7 REGULATIONS?

01:49PM 8 A. A VERY LOW COMPLEXITY PROCESSING PATIENT SAMPLES, RUNNING

01:50PM 9 QC'S. IT WAS THE BASIC OPERATIONS OF RUNNING LAB TESTS.

01:50PM 10 Q. WELL, DON'T SELL YOURSELF SHORT. YOU HAD TO HAVE A

01:50PM 11 FOUR-YEAR DEGREE AND A SCIENCE BACKGROUND; CORRECT?

01:50PM 12 A. YES, A BACHELOR'S DEGREE.

01:50PM 13 Q. YES. WHICH YOU HAVE?

01:50PM 14 A. YES.

01:50PM 15 Q. AND WHEN YOU MOVED OVER TO THE LAB, I THINK YOU MENTIONED

01:50PM 16 THAT YOU ACTUALLY INTERACTED WITH DR. ROSENDORFF A BIT?

01:50PM 17 A. YES.

01:50PM 18 Q. AND YOU UNDERSTOOD THAT HE WAS THE LABORATORY DIRECTOR?

01:50PM 19 A. YES.

01:50PM 20 Q. AND DID YOU UNDERSTAND, BROADLY SPEAKING, THAT HE HAD SORT

01:50PM 21 OF ULTIMATE REGULATORY RESPONSIBILITY FOR THE LAB?

01:50PM 22 A. YES.

01:50PM 23 Q. AND ARE YOU AWARE THAT THERE ARE DIFFERENT CLASSIFICATIONS

01:51PM 24 OF LABS UNDER CLIA?

01:51PM 25 A. NO.

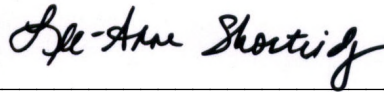
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: SEPTEMBER 15, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 9
)
ELIZABETH A. HOLMES,) SEPTEMBER 21, 2021
)
DEFENDANT.) PAGES 1240 - 1449
_____)

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

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TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
LANCE A. WADE
KATHERINE TREFZ
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BY: ADELAIDA HERNANDEZ

OFFICE OF THE U.S. ATTORNEY
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MADDI WACHS, PARALEGAL

WILLIAMS & CONNOLLY
BY: TIMIKA ADAMS-SHERMAN, PARALEGAL

TBC
BY: BRIAN BENNETT, TECHNICIAN

INDEX OF PROCEEDINGS

GOVERNMENT'S:

SUREKHA GANGAKHEDKAR

CROSS-EXAM BY MR. WADE (RES.) P. 1261

REDIRECT EXAM BY MR. BOSTIC P. 1366

AUDRA ZACHMAN

DIRECT EXAM BY MR. BOSTIC P. 1378

CROSS-EXAM BY MS. TREFZ P. 1414

REDIRECT EXAM BY MR. BOSTIC P. 1430

B [REDACTED] G [REDACTED]

DIRECT EXAM BY MR. LEACH P. 1436

01:30PM 1 FIRST RECEIVED THIS RESULT?

01:30PM 2 A. I REMEMBER COMMUNICATING TO B [REDACTED] THAT IT WAS LOOKING
01:30PM 3 AS THOUGH THIS WAS A NONVIABLE PREGNANCY, WHICH WOULD MAKE IT
01:30PM 4 HER FOURTH LOSS, AND I WAS WANTING TO REACH OUT TO HER TO SEE
01:30PM 5 IF SHE HAD ALREADY EXPERIENCED EVIDENCE OF A LOSS OF PREGNANCY.

01:30PM 6 Q. AND WHAT INFORMATION DID YOU GET BACK FROM MS. G [REDACTED] IN
01:30PM 7 RESPONSE TO THAT QUESTION?

01:30PM 8 A. THAT, NO, SHE HADN'T EXPERIENCED ANY SYMPTOMS OF A LOSS OF
01:30PM 9 PREGNANCY; THAT THERE WAS NO MEDICAL INTERVENTION THAT NEEDED
01:30PM 10 TO TAKE PLACE FOR HER WELL BEING; AND SURPRISE, SADNESS.

01:31PM 11 Q. DID YOU MAKE A DECISION AT THAT POINT TO CONTINUE WITH
01:31PM 12 PERIODIC HCG TESTING?

01:31PM 13 A. YES. IN PREGNANCY LOSSES WE NEED TO CONFIRM THAT ALL OF
01:31PM 14 THE PREGNANCY TISSUE HAS BEEN ELIMINATED FROM THE BODY, SO WE
01:31PM 15 FOLLOW THE HCG'S BACK DOWN TO LESS THAN 5.

01:31PM 16 Q. AND IS THAT WHAT YOU WERE EXPECTING TO SEE IN THOSE
01:31PM 17 CONTINUED HCG TESTS?

01:31PM 18 A. YES.

01:31PM 19 Q. THE NEXT TEST FOR MS. G [REDACTED] WAS ON OCTOBER 6TH, 2014; IS
01:31PM 20 THAT CORRECT?

01:31PM 21 A. CORRECT.

01:31PM 22 Q. AND THE TEST WAS PERFORMED BY WHICH LAB?

01:31PM 23 A. SONORA.

01:31PM 24 Q. AND WHAT WAS THE HCG VALUE ON THAT DATE?

01:31PM 25 A. 9559.

02:21PM 1 MS. TREFZ: OKAY. NO FURTHER QUESTIONS, YOUR HONOR.

02:21PM 2 THE COURT: MR. BOSTIC?

02:21PM 3 MR. BOSTIC: BRIEFLY, YOUR HONOR.

02:21PM 4 **REDIRECT EXAMINATION**

02:21PM 5 BY MR. BOSTIC:

02:21PM 6 Q. GOOD AFTERNOON AGAIN, DR. ZACHMAN.

02:21PM 7 A. GOOD AFTERNOON.

02:21PM 8 Q. JUST NOW YOU HAD A BRIEF DISCUSSION WITH DEFENSE COUNSEL
02:21PM 9 ABOUT A STUDY THAT WAS CONDUCTED REGARDING THERANOS HCG TEST
02:21PM 10 RESULTS.

02:21PM 11 DO YOU RECALL THAT?

02:21PM 12 A. I DO.

02:21PM 13 Q. AND WHEN THE RESULTS OF THAT STUDY WERE COMPLETE, DID YOU
02:22PM 14 HAVE AN OPPORTUNITY TO REVIEW THOSE RESULTS?

02:22PM 15 A. BRIEFLY.

02:22PM 16 Q. IN SUM, DID THOSE RESULTS RESTORE YOUR CONFIDENCE IN
02:22PM 17 THERANOS'S ABILITY TO DELIVER ACCURATE HCG RESULTS?

02:22PM 18 A. NO.

02:22PM 19 Q. AND WHY NOT IF YOU RECALL?

02:22PM 20 A. MY CARE OF B [REDACTED], AND THE VALUES THAT I RECEIVED AT
02:22PM 21 THAT TIME WERE VERY IMPACTFUL TO ME AS A PROVIDER AND PERHAPS
02:22PM 22 EMPHASIZING TO HER AS A WOMAN, AND SO THERE WASN'T MUCH THAT
02:22PM 23 COULD HAVE RESTORED MY FAITH AT THAT TIME.

02:22PM 24 Q. DO YOU RECALL HOW MANY PEOPLE PARTICIPATED IN THAT STUDY
02:22PM 25 APPROXIMATELY OR HOW MANY SAMPLES WERE INVOLVED?

02:40PM 1 A. I WENT IN FOR MY VISIT, AND THEY GIVE YOU A BAG OF STUFF
02:40PM 2 WHEN YOU'RE A NEW MOM, ALL OF THE GOODIES. SO I GOT MY BAG,
02:40PM 3 AND WE HAD THIS CONVERSATION. AND THEN THE LAB RESULTS HAD
02:40PM 4 COME IN AT THE END OF THE VISIT, AND SHE TOLD ME YOUR NUMBERS
02:40PM 5 ARE FALLING, UNFORTUNATELY.

02:40PM 6 THAT SIGNIFIED TO ME THAT I WAS MISCARRYING.

02:41PM 7 Q. AND WHEN DR. ZACHMAN TOLD YOU THAT YOUR NUMBERS WERE
02:41PM 8 FALLING, DID YOU UNDERSTAND THAT TO BE A REFERENCE TO THE HCG
02:41PM 9 TEST?

02:41PM 10 A. YES.

02:41PM 11 Q. AND HAD YOU HAD EXPERIENCE WITH FALLING HCG TESTS FROM
02:41PM 12 YOUR PRIOR MISCARRIAGES?

02:41PM 13 A. YES.

02:41PM 14 Q. DID YOU DISCUSS WITH -- BASED ON THE FALLING NUMBERS THAT
02:41PM 15 DR. ZACHMAN DESCRIBED TO YOU, DID YOU AND SHE DISCUSS POTENTIAL
02:41PM 16 TREATMENT OPTIONS?

02:41PM 17 A. YES.

02:41PM 18 Q. AND WHAT DID YOU DISCUSS?

02:41PM 19 A. THE WAYS TO TERMINATE A PREGNANCY, THE OPTIONS, YOU CAN
02:41PM 20 TAKE THE MEDICATION AND D&C OR JUST LET YOUR BODY GO THROUGH IT
02:41PM 21 NATURALLY.

02:41PM 22 Q. AND DID YOU AND DR. ZACHMAN ALSO DISCUSS GETTING RETESTED?

02:41PM 23 A. YES.

02:41PM 24 Q. LET ME DRAW YOUR ATTENTION TO WHAT HAS BEEN ADMITTED INTO
02:41PM 25 EVIDENCE AS EXHIBIT 3305.

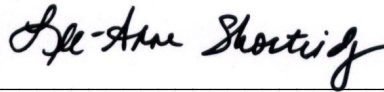
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PLAINTIFF,) SAN JOSE, CALIFORNIA
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VS.) VOLUME 11
)
ELIZABETH A. HOLMES,) SEPTEMBER 24, 2021
)
DEFENDANT.) PAGES 1686 - 1888
_____)

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GOVERNMENT'S:

ADAM ROSENDORFF

DIRECT EXAM BY MR. BOSTIC

P. 1702

09:21AM 1 Q. AND WAS THERE SOMEONE AT THE COMPANY THAT YOU REPORTED TO?

09:21AM 2 A. YES.

09:21AM 3 Q. AND WHO DID YOU REPORT TO?

09:21AM 4 A. SUNNY BALWANI.

09:21AM 5 Q. AND WHO WAS ABOVE MR. BALWANI AT THE COMPANY, IF ANYONE?

09:21AM 6 A. ELIZABETH HOLMES.

09:21AM 7 Q. DID THERE COME A TIME WHEN THERANOS BEGAN OFFERING ITS

09:21AM 8 BLOOD TEST SERVICES TO THE PUBLIC?

09:21AM 9 A. YES.

09:21AM 10 Q. AND DO YOU RECALL APPROXIMATELY WHEN THAT WAS?

09:21AM 11 A. IT WAS EARLY IN SEPTEMBER OF 2013. I THINK THE 9TH OF

09:21AM 12 SEPTEMBER.

09:21AM 13 Q. AND DID THERANOS CONTINUE OFFERING BLOOD TESTING SERVICES

09:22AM 14 TO THE PUBLIC THROUGHOUT THE REST OF YOUR TIME AT THE COMPANY?

09:22AM 15 A. YES.

09:22AM 16 Q. AND LEADING UP TO THAT COMMERCIAL LAUNCH, SO AFTER YOU

09:22AM 17 JOINED THE COMPANY BUT BEFORE EARLY SEPTEMBER 2013, WHAT KIND

09:22AM 18 OF WORK WERE YOU DOING AT THE COMPANY?

09:22AM 19 A. I WAS ACTING ESSENTIALLY AS A CONSULTANT. SO A LOT OF

09:22AM 20 WHAT I WAS DOING WAS TELLING THE R&D GROUP WHAT KIND OF

09:22AM 21 MEASUREMENT RANGE WE NEEDED FOR THE TESTS BASED ON VALUES THAT

09:22AM 22 WOULD BE USEFUL TO CLINICIANS FOR MAKING MEDICAL DECISIONS.

09:22AM 23 I DID CONSULT WITH THE EXECUTIVES IN TERMS OF THE TESTS

09:22AM 24 THAT WE KNEW THAT WE SHOULD BE OFFERING.

09:22AM 25 I DON'T RECALL THE OTHER DUTIES SPECIFICALLY.

09:22AM 1 Q. YOU SAID WHEN YOU FIRST JOINED THE COMPANY YOU HAD LIMITED
09:23AM 2 KNOWLEDGE ABOUT THE TECHNOLOGY. DID THAT KNOWLEDGE INCREASE
09:23AM 3 AFTER YOU JOINED THE COMPANY?

09:23AM 4 A. IT DID.

09:23AM 5 Q. LET'S TALK ABOUT THE THERANOS DEVICES THAT YOU WERE
09:23AM 6 FAMILIAR WITH.

09:23AM 7 FIRST, DID YOU BECOME FAMILIAR WITH A DEVICE CALLED
09:23AM 8 EDISON?

09:23AM 9 A. YES.

09:23AM 10 Q. AND WHAT WAS THE EDISON DEVICE?

09:23AM 11 A. THE EDISON WAS A SMALL BLACK BOX THAT WAS DESIGNED TO RUN
09:23AM 12 ONE TEST AT A TIME. THE CATEGORY OF TESTS WERE IMMUNOASSAYS.
09:23AM 13 THESE ARE USUALLY LARGER MOLECULES THAT ARE NOT ABLE TO BE
09:23AM 14 MEASURED ON ANALYZERS AND THAT RELIED ON ANTIBODIES FOR THEIR
09:23AM 15 PROTECTION.

09:23AM 16 Q. AND DID THERANOS USE THE EDISON DEVICE DURING YOUR TIME AS
09:23AM 17 LAB DIRECTOR?

09:23AM 18 A. YES.

09:23AM 19 Q. AND DID THERANOS USE THE EDISON TO TEST PATIENT SAMPLES?

09:23AM 20 A. YES.

09:23AM 21 Q. AND WHO MANUFACTURED THE EDISON?

09:24AM 22 A. THE EDISON WAS MANUFACTURED BY THERANOS IN THEIR NEWARK
09:24AM 23 FACILITY.

09:24AM 24 Q. DURING YOUR TIME AT THE COMPANY, DID YOU BECOME FAMILIAR
09:24AM 25 WITH ANY OTHER THERANOS MANUFACTURED BLOOD ANALYZERS?

09:24AM 1 A. I HAD BEEN TOLD ABOUT AN INSTRUMENT CALLED THE MINILAB
09:24AM 2 THAT WAS IN DEVELOPMENT. IT WAS BEING DESIGNED FOR GENERAL
09:24AM 3 CHEMISTRY ASSAYS.
09:24AM 4 AND ALSO ABOUT AN INSTRUMENT CALLED THE 4S, WHICH WOULD BE
09:24AM 5 ABLE TO DO COMPLETE BLOOD COUNTS AMONG OTHER ASSAYS.
09:24AM 6 I WAS NOT FAMILIAR WITH THE INTENDED CAPABILITY OF THOSE
09:24AM 7 INSTRUMENTS IN DEVELOPMENT.
09:24AM 8 Q. YOU SAID YOU WERE TOLD ABOUT THOSE INSTRUMENTS. DID YOU
09:24AM 9 EVER DO ANY WORK ON DEVELOPING THOSE INSTRUMENTS?
09:24AM 10 A. NO.
09:24AM 11 Q. AND DID YOU EVER DO ANY WORK ON DEVELOPING OR VALIDATING
09:24AM 12 ASSAYS TO RUN ON THOSE INSTRUMENTS?
09:24AM 13 A. NO.
09:24AM 14 Q. DID YOU EVER SEE EITHER OF THOSE INSTRUMENTS?
09:25AM 15 A. NO.
09:25AM 16 Q. WAS EITHER OF THOSE INSTRUMENTS THAT YOU MENTIONED EVER
09:25AM 17 USED FOR PATIENT TESTING DURING YOUR TIME AT THE COMPANY?
09:25AM 18 A. NO.
09:25AM 19 Q. DID THERANOS RUN ALL OF ITS CLINICAL PATIENT TESTS ON THE
09:25AM 20 EDISON ANALYZER?
09:25AM 21 A. NO, JUST A HANDFUL OF IMMUNOASSAYS. THEY RAN GENERAL
09:25AM 22 CHEMISTRY TESTS ON THE SIEMENS ADVIA USING A LABORATORY
09:25AM 23 DEVELOPED TEST.
09:25AM 24 Q. AND WHAT DOES "LABORATORY DEVELOPED TESTS" MEAN?
09:25AM 25 A. LABORATORY DEVELOPED TESTS IS A TEST DEVELOPED WITHIN A

09:25AM 1 SINGLE LABORATORY THAT IS NOT FDA APPROVED. IT USES CUSTOM
09:26AM 2 REAGENTS EITHER MANUFACTURED BY THE LABORATORY OR PURCHASED
09:26AM 3 ELSEWHERE, AND IT HAS TO MEET CERTAIN PERFORMANCE
09:26AM 4 SPECIFICATIONS PER CLIA BEFORE IT CAN BE USED FOR PATIENT CARE.
09:26AM 5 Q. AND THE SIEMENS ADVIA THAT YOU MENTIONED, IS IT
09:26AM 6 MANUFACTURED BY THERANOS?
09:26AM 7 A. NO. IT'S MANUFACTURED BY SIEMENS.
09:26AM 8 Q. WHY DIDN'T THERANOS CONDUCT ALL OF ITS PATIENT TESTING ON
09:26AM 9 THE EDISON?
09:26AM 10 A. BECAUSE THE EDISON WAS NOT INTENDED TO -- DESIGNED OR
09:26AM 11 INTENDED TO DETECT GENERAL CHEMISTRY SUBSTANCES SUCH AS GLUCOSE
09:26AM 12 OR SODIUM.
09:26AM 13 IT WAS DESIGNED TO DETECT LARGER PEPTIDES AND OTHER
09:26AM 14 ANALYTES, YEAH.
09:26AM 15 Q. DID THERANOS MAKE ANY CHANGES TO THE SIEMENS ADVIA THAT IT
09:27AM 16 USED FOR PATIENT TESTING?
09:27AM 17 A. YES.
09:27AM 18 Q. AND WHAT WERE THE NATURE OF THOSE CHANGES?
09:27AM 19 A. BECAUSE OF THE SMALL SAMPLE SIZE THAT WAS BEING ACQUIRED
09:27AM 20 IN THE CAPILLARY TUBE AND NANOTAINER DEVICES, THE SIEMENS ADVIA
09:27AM 21 WAS NOT ABLE TO ASPIRATE THAT SAMPLE INTO THE INSTRUMENT
09:27AM 22 BECAUSE THE PROBE COULDN'T GO DOWN FAR ENOUGH AND TO SUCK UP
09:27AM 23 THE SAMPLE.
09:27AM 24 SO THEY DEVELOPED WHAT THEY CALLED THE T-CUP, WHICH WOULD
09:27AM 25 ESSENTIALLY RAISE THE LEVEL OF THAT SAMPLE TO A POINT WHERE THE

09:27AM 1 PROBE OR THE ASPIRATOR COULD SUCK IT UP INTO THE INSTRUMENT.

09:27AM 2 THEY ALSO CHANGED WAVELENGTHS AND DETECTION TIMES ON THE

09:27AM 3 INSTRUMENT, WHICH YOU'RE ABLE TO DO ON THE SO-CALLED OPEN

09:27AM 4 CHANNELS ON THE INSTRUMENTS. SO MOST OF THE TESTS RELY ON

09:27AM 5 ABSORBANCE AT A SPECIFIC WAVELENGTH.

09:28AM 6 Q. AND TO USE THOSE THERANOS MODIFIED SIEMENS ADVIA, DID THEY

09:28AM 7 INSERT BLOOD SAMPLES INTO THE MACHINE OR WERE THERE OTHER STEPS

09:28AM 8 THAT CAME BEFORE?

09:28AM 9 A. NO. THE CTN DEVICE WOULD BE SPUN DOWN AND THEN THE SERUM

09:28AM 10 OR PLASMA WOULD BE REMOVED. THAT'S THE CLEAR PORTION OF THE

09:28AM 11 SAMPLE THAT IS FREE OF RED BLOOD CELLS.

09:28AM 12 THAT PORTION WOULD THEN BE DILUTED EITHER WITH SALINE OR

09:28AM 13 WATER TO GIVE A VOLUME THAT WAS COMPATIBLE WITH THE THERANOS

09:28AM 14 TEST.

09:28AM 15 Q. I'LL ASK YOU TO LOOK AT THE BINDER IN FRONT OF YOU.

09:28AM 16 THAT'S THE FIRST TAB, 939.

09:28AM 17 THE GOVERNMENT WOULD LIKE TO OFFER THIS INTO EVIDENCE,

09:28AM 18 YOUR HONOR.

09:28AM 19 I UNDERSTAND THE DEFENSE HAVE STIPULATED.

09:28AM 20 MR. WADE: WE HAVE, YOUR HONOR.

09:28AM 21 THE COURT: IT'S ADMITTED.

09:28AM 22 WOULD YOU LIKE IT PUBLISHED?

09:29AM 23 MR. BOSTIC: YES, PLEASE.

09:29AM 24 THE COURT: IT MAY BE PUBLISHED.

09:29AM 25 (GOVERNMENT'S EXHIBIT 939 WAS RECEIVED IN EVIDENCE.)

09:33AM 1 SCHEMES AND WAYS THAT THIS WAS GOING TO BE EXECUTED.

09:33AM 2 Q. OKAY. DID -- LET'S SEE. WERE ALL OF THE SIEMENS MODIFIED
09:34AM 3 DEVICES AT THERANOS MODIFIED IN THIS SAME WAY?

09:34AM 4 A. I BELIEVE THAT THE THERANOS LABORATORY DEVELOPED TESTS
09:34AM 5 WERE DIVIDED AMONGST A NUMBER OF SIEMENS INSTRUMENTS.

09:34AM 6 THE GOAL INITIALLY WAS TO HAVE ONE SIEMENS INSTRUMENT BE
09:34AM 7 ABLE TO RUN ALL OF THE THERANOS LABORATORY DEVELOPED TESTS, BUT
09:34AM 8 I DON'T THINK WE WERE ABLE TO DO THAT, SO WE HAD TO DIVVY IT UP
09:34AM 9 AMONGST THE DIFFERENT INSTRUMENTS.

09:34AM 10 Q. DID THE CLINICAL LAB AT THERANOS USE ANY THIRD PARTY
09:34AM 11 DEVICES, ANY NON-THERANOS DEVICES THAT WERE UNMODIFIED?

09:34AM 12 A. YES, THEY USED THE SIEMENS ADVIA 1800 IN AN UNMODIFIED
09:34AM 13 MANNER TO BE RUN WITH VENOUS DRAWS FROM VACUTAINERS. THERE WAS
09:34AM 14 AN INSTRUMENT CALLED THE IMMULITE THAT DID IMMUNOASSAY WITH
09:35AM 15 VENOUS DRAWS. THERE WAS ABBOTT CELLDYNE RUBY THAT DID COMPLETE
09:35AM 16 BLOOD COUNTS. THERE WAS AN INSTRUMENT FOR BLOOD LEAD
09:35AM 17 MONITORING. THERE WAS AN INSTRUMENT TO MEASURE AUTO
09:35AM 18 ANTIBODIES. I DON'T REMEMBER THE MANUFACTURER.

09:35AM 19 SO THERE WERE A NUMBER OF THIRD PARTY INSTRUMENTS, YEAH.

09:35AM 20 Q. AND THE INSTRUMENTS THAT YOU JUST LISTED, TO YOUR
09:35AM 21 KNOWLEDGE, DID THEY CONTAIN ANY THERANOS-SPECIFIC ENGINEERING
09:35AM 22 OR MODIFICATIONS?

09:35AM 23 A. NO. IT WAS JUST THE ADVIA.

09:35AM 24 Q. AT THE THERANOS LOCATION PHYSICALLY, CAN YOU TELL US WHERE
09:36AM 25 THE LAB DEVICES WERE IN THE BUILDING?

01:29PM 1 COMPLETELY NORMAL. DR. STAMPS SAID THAT POTASSIUM IS A TRICKY
01:29PM 2 ONE TO COLLECT BECAUSE OF CLOTTING AND SUCH. HE ALSO MENTIONED
01:29PM 3 THAT HE IS WILLING TO SHARE THE SPECIFIC PATIENT INFORMATION
01:29PM 4 AND EXPLAIN THE EXPERIENCE IF SOMEONE WANTED TO REACH OUT TO
01:29PM 5 HIM."

01:29PM 6 DID I READ THAT CORRECTLY?

01:29PM 7 A. YES.

01:29PM 8 Q. WHAT IS POTASSIUM?

01:29PM 9 A. POTASSIUM IS A -- IT'S AN ION. IT'S A CHEMICAL ELEMENT
01:30PM 10 THAT IN A PATIENT IS IMPORTANT FOR CARDIAC FUNCTION AND NERVE
01:30PM 11 CONDUCTION.

01:30PM 12 Q. AND WOULD AN ABNORMALLY HIGH POTASSIUM RESULT BE A CAUSE
01:30PM 13 FOR HARM AND IMMEDIATE RETEST?

01:30PM 14 A. YES. CRITICAL HIGH TEST RESULTS COULD INDICATE THAT THE
01:30PM 15 PATIENT IS AT RISK FOR A HEART RHYTHM PROBLEM. IT'S CALLED
01:30PM 16 ARRYTHMIA.

01:30PM 17 Q. LET'S LOOK AT PAGE 1 OF THIS EXHIBIT. LET'S ZOOM IN ON
01:30PM 18 THE MIDDLE THIRD IF WE CAN.

01:30PM 19 DANIEL YOUNG WRITES, "I'M NOT SURE THAT THIS DOCTOR WAS
01:31PM 20 ASKING ABOUT THE CRITICAL VALUE FOR POTASSIUM. CRITICAL VALUE
01:31PM 21 COMES FROM CLINICAL GUIDANCE DOCUMENTS AND CARE GUIDELINES, NOT
01:31PM 22 FROM R&D."

01:31PM 23 DO YOU SEE THAT?

01:31PM 24 A. YES.

01:31PM 25 Q. AND LET'S LOOK AT THE MESSAGE ABOVE THAT FROM MR. BALWANI.

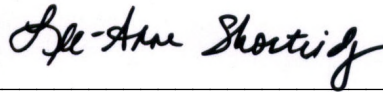
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CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: SEPTEMBER 24, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 19
)
ELIZABETH A. HOLMES,) OCTOBER 14, 2021
)
DEFENDANT.) PAGES 3538 - 3757
_____)

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
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ALSO PRESENT: FEDERAL BUREAU OF INVESTIGATION
BY: ADELAIDA HERNANDEZ

OFFICE OF THE U.S. ATTORNEY
BY: LAKISHA HOLLIMAN, PARALEGAL
MADDI WACHS, PARALEGAL

WILLIAMS & CONNOLLY
BY: TIMIKA ADAMS-SHERMAN, PARALEGAL

TBC
BY: BRIAN BENNETT, TECHNICIAN

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10:47AM 1 A. YES, MY ROLE DID CHANGE. OBVIOUSLY WE WERE NOT EXPANDING
10:47AM 2 BEYOND THE 41 STORES THAT WE ALREADY HAD.

10:47AM 3 AND BECAUSE OF THE ARTICLE, YOU KNOW, I TOOK A STEP BACK
10:47AM 4 AS WE WERE NOT EXPANDING ANYMORE, WE WERE JUST SIMPLY
10:47AM 5 MONITORING, AND OTHERS AT THE COMPANY TOOK LEAD.

10:48AM 6 Q. AT SOME POINT, DID WALGREENS STOP OFFERING THERANOS BLOOD
10:48AM 7 TESTING SERVICES? CAN YOU STILL GO TO WALGREENS AND GET
10:48AM 8 THERANOS BLOOD TESTING SERVICES?

10:48AM 9 A. YES, WE DID STOP AT ONE POINT.

10:48AM 10 Q. YOU DID STOP. SORRY, I ASKED YOU TWO QUESTIONS.

10:48AM 11 DO YOU RECALL ROUGHLY WHEN YOU STOPPED?

10:48AM 12 A. WE STOPPED ONE OF THE SERVICES IN JANUARY OF 2016 IN ONE
10:48AM 13 OF THE STORES.

10:48AM 14 AND THEN THE REST OF THE STORES WERE TURNED OFF SOMEWHERE
10:48AM 15 IN JUNE OF THAT YEAR, 2016.

10:48AM 16 Q. THANK YOU.

10:48AM 17 YOUR HONOR, MAY I APPROACH?

10:48AM 18 THE COURT: YES.

10:49AM 19 MR. SCHENK: (HANDING.)

10:49AM 20 Q. MR. BALWANI, I'VE HANDED YOU WHAT I'VE MARKED AS
10:49AM 21 EXHIBIT 5387C, AND THIS DOCUMENT IS 16 PAGES AND CONTAINS SOME
10:49AM 22 TEXT MESSAGES.

10:49AM 23 YOUR HONOR, I BELIEVE THE PARTIES ARE AGREEING TO ADMIT

10:49AM 24 THIS BASED ON A STIPULATION.

10:49AM 25 MR. DOWNEY: THAT'S CORRECT, YOUR HONOR.

10:49AM 1 THE COURT: ALL RIGHT. THIS IS -- I'M SORRY, IS
10:49AM 2 THIS 5387C DID YOU SAY?
10:49AM 3 MR. SCHENK: YES, YOUR HONOR.
10:49AM 4 THE COURT: THAT'S ADMITTED, AND WITHOUT OBJECTION
10:49AM 5 IT MAY BE PUBLISHED.
10:49AM 6 MR. SCHENK: THANK YOU.
10:49AM 7 (GOVERNMENT'S EXHIBIT 5387 WAS RECEIVED IN EVIDENCE.)
10:49AM 8 BY MR. SCHENK:
10:49AM 9 Q. MR. JHAVERI, I'D LIKE TO READ NOW SOME TEXT MESSAGES WITH
10:49AM 10 YOU. I'LL HAVE YOU START, AND THEN IF YOU'LL FOLLOW ALONG WITH
10:49AM 11 ME, I JUST WANT TO IDENTIFY THE COLUMNS FOR YOU.
10:50AM 12 FIRST, THESE ARE NOT YOUR TEXT MESSAGES; IS THAT RIGHT?
10:50AM 13 A. NO, THESE ARE NOT MY TEXT MESSAGES.
10:50AM 14 Q. ARE THESE TEXT MESSAGES SENT BETWEEN MR. BALWANI AND
10:50AM 15 MS. HOLMES?
10:50AM 16 A. YES, IT APPEARS TO BE.
10:50AM 17 Q. SO THERE'S A COLUMN WITH A DATE THAT IS THE THIRD COLUMN,
10:50AM 18 DO YOU SEE THAT, AND THEY BEGIN MARCH OF 2010?
10:50AM 19 A. YES, SIR.
10:50AM 20 Q. AND THE NEXT COLUMN IS THE CONTENT.
10:50AM 21 DO YOU SEE THAT?
10:50AM 22 A. YES.
10:50AM 23 Q. AND THEN THE NEXT TWO COLUMNS ARE SENDER AND RECIPIENT.
10:50AM 24 SO THE FIRST NAME IS WHO SENT THE MESSAGE, AND THE SECOND IS
10:50AM 25 WHO RECEIVED IT; IS THAT RIGHT?

10:50AM 1 A. THAT'S CORRECT.

10:50AM 2 Q. OKAY. I'D LIKE TO READ THEM WITH YOU. IF YOU WOULD, WHY

10:50AM 3 DON'T YOU PLEASE START?

10:50AM 4 A. SURE.

10:50AM 5 "WE HAVE AN OPPORTUNITY TO PUT TELEMEDICINE IN OUR

10:50AM 6 CONTRACT WITH WAG."

10:50AM 7 Q. AND IS THAT A MESSAGE THAT MR. BALWANI SENT?

10:50AM 8 A. YES.

10:50AM 9 Q. AND THEN IT LOOKS LIKE MS. HOLMES RESPONDS, "WE SHOULD

10:50AM 10 NAIL THAT."

10:51AM 11 "AND ACTUALLY KICK IT OFF IN OUR MEETING WITH MAYO."

10:51AM 12 "AND POSSIBLY CLEVELAND."

10:51AM 13 "AND THEN BUILD THE TEAM HERE AS WE HIRE."

10:51AM 14 "THEY WON'T BE READY OVERNIGHT ANYWAY."

10:51AM 15 A. "CLEVELAND CLINIC."

10:51AM 16 Q. "YES."

10:51AM 17 MR. JHAVERI, I THINK THE NEXT ONE IS YOU.

10:51AM 18 A. YES.

10:51AM 19 "WE WILL TALK, WE WILL BRING THIS UP AND NEGOTIATE AS LAST

10:51AM 20 THING ONCE ALL ELSE IS DONE."

10:51AM 21 Q. "YES."

10:51AM 22 A. "I OPENED THE DOOR."

10:51AM 23 Q. "GREAT."

10:51AM 24 A. "WILL TELL U MORE IN PERSON."

10:51AM 25 Q. "K."

10:51AM 1 A. "THEY WERE DROOLING OVER CLEVELAND CLINIC ANNOUNCEMENT."

10:51AM 2 "WE DID TESTER."

10:51AM 3 "YESTERDAY."

10:51AM 4 Q. "EVERYONE IS."

10:51AM 5 "HOPEFULLY THEY'RE OFF PEER REVIEW."

10:51AM 6 A. "WHICH IS WHY WE NEED TO DO GOOD-BYE CLEVELAND CLINIC."

10:52AM 7 Q. "EXACTLY."

10:52AM 8 "ON CLEVELAND CLINIC."

10:52AM 9 AND THEN IF WE CAN TURN TO PAGE 2 AT THE TOP.

10:52AM 10 A. "GOING THRU CVS CONTRACT. WE CAN'T WORK WITH WAG OR CVS."

10:52AM 11 BOTH ARE SAME."

10:52AM 12 "AND SWY."

10:52AM 13 Q. "CAN'T FORGET THAT."

10:52AM 14 A. "WE NEED TO THINK THRU OUR DISCUSSION ON THIS TOPIC."

10:52AM 15 Q. "MEANING TOMORROW'S?"

10:52AM 16 A. "NO. OUR OWN STORES."

10:52AM 17 Q. "EXACTLY."

10:52AM 18 A. "I AM THINKING. IT WILL DEPEND ON DISCUSSION TOMORROW

10:52AM 19 WITH WAG."

10:52AM 20 Q. AND NOW WE'RE TURNING TO THE THIRD PAGE.

10:52AM 21 A. "IF CONTRACT TERMS AND WE DON'T HAVE 1000 STORES. WHAT

10:53AM 22 HAPPENS TO 50M REMAINING INNOVATION PAYMENT."

10:53AM 23 Q. "DEPENDS ON WHY TERMS."

10:53AM 24 "SCALE NOW IF NEED."

10:53AM 25 A. "SO FORCE BUILD 1000 STORES? I DON'T THINK THAT'S

10:53AM 1 INTELLIGENT."

10:53AM 2 "WITH CONTRACT EXPIRING IN AUGUST OF 2017 MEANS BUILDING

10:53AM 3 OUT 1000 BY FEBRUARY 2016. NOT GOOD FOR US."

10:53AM 4 "THERE ARE EQUAL NUMBER OF CVS AND WAG IN NEW YORK STATE

10:53AM 5 BTW."

10:53AM 6 Q. AND NOW WE'RE TURNING TO PAGE 4.

10:53AM 7 A. "WHEN WE LAUNCH IN NEW YORK WE CAN LAUNCH WITH CVS AND

10:53AM 8 GIVE THEM ONCE WE HAVE 50 E DONE, WE WILL BE INVINCIBLE.

10:53AM 9 Q. "AGREE."

10:53AM 10 "IF TERMS BECAUSE WE TERM THEN WE RETURN. THEY TERM AND

10:54AM 11 WE DON'T WANT TO WE KEEP."

10:54AM 12 A. "WE DON'T WANT 1000 STORES WITH ASSHOLES."

10:54AM 13 "200 WILL BE ENOUGH TO PROVE OUR POINT."

10:54AM 14 Q. "I KNOW."

10:54AM 15 A. "I WILL SAY WE KEEP 25 NO MATTER WHAT."

10:54AM 16 Q. "BUT THEN DEPENDING ON WHO TERMS SHOULD WORK."

10:54AM 17 "AGREE."

10:54AM 18 A. "YES."

10:54AM 19 "BUT IF NATURAL TERMS THEN WE RETURN 25."

10:54AM 20 "IF THEY DON'T BUILD 500 WE KEEP 25."

10:54AM 21 "CORRECT."

10:54AM 22 Q. "YES."

10:54AM 23 "NATURAL MEANING WE BOTH DECIDE NOT TO REVIEW? ALSO IF WE

10:54AM 24 WANT TO RENEW BUT THEY DON'T."

10:54AM 25 A. "I WOULD LIKE TO KEEP SIMPLE. IF THEY BUILD MINIMUM 500

10:54AM 1 THEY GET ALL 50. IF THEY DON'T WE KEEP MINIMUM 25. I CAN ALSO

10:55AM 2 SAY IF THEY DON'T BUILD 500 WE KEEP ALL 50 SINCE WE BANKED ON

10:55AM 3 THEM."

10:55AM 4 "GOING TO WAG MEETING."

10:55AM 5 "DONE. CALL WHEN U HAVE 30 MINUTES."

10:55AM 6 Q. "AGREE WITH ABOVE."

10:55AM 7 "WILL CALL SOON."

10:55AM 8 A. "MOSTLY TERRIBLE MEETING BUT NET NET IS WHAT WE WANT."

10:55AM 9 "LOVE YOU TOO."

10:55AM 10 Q. THE -- I'M SORRY. THAT'S YOU.

10:55AM 11 A. "THE POINT ABOUT NARROWING DOWN MENU TO HIT HIGH FS

10:55AM 12 PERCENTAGE CAME TO ME LIKE GIFT OF GOD."

10:55AM 13 Q. AND NOW WE'RE TURNING TO PAGE 5.

10:55AM 14 A. "I WAS MEDITATING ON THIS MEETING ALL NIGHT AND ALL DAY."

10:55AM 15 Q. "YOU NAILED IT."

10:55AM 16 A. "WE MUST HIT OUR VOLUME GOALS NOW."

10:56AM 17 "WE NEED TO MAKE IT A MATTER OF LIFE AND DEATH."

10:56AM 18 "SURVIVAL. WE MUST NOT LOSE."

10:56AM 19 Q. NOW WE'RE TURNING TO PAGE 6.

10:56AM 20 A. "BTW I SENT CVS DOCUMENT TO HEATHER AND CHRIS ON SATURDAY

10:56AM 21 AND HAVEN'T RECEIVED ANY FEEDBACK FROM THEM."

10:56AM 22 Q. "OK I WILL BE THERE (LANDING IN 2 HOURS AND 10 MINUTES)

10:56AM 23 AND CAN MEET WITH ANY CANDIDATES WE THINK MAKES SENSE. NOTHING

10:56AM 24 IS ON MY CALENDAR. DO YOU WANT ME TO EMAIL HEATHER AND CHRIS

10:56AM 25 ON TURNING THE CVS DOCUMENT?"

10:56AM 1 A. "NO."

10:56AM 2 Q. "ARE THEY HELPING YOU ON WAG CONTRACT?"

10:56AM 3 A. "NO ONE ON WAG CONTRACT BEING WANT ANYONE ON WAG CONTRACT.

10:56AM 4 THIS U AND I NEED CLOSE OUR CHESTS."

10:56AM 5 "DON'T WANT."

10:56AM 6 Q. NOW WE'RE TURNING TO PAGE 7.

10:57AM 7 A. "I PRESENTED CA BUY ASKED ME WHY WE WOULDN'T DO CA WITH

10:57AM 8 WAG 'OUT OF CURIOSITY.'"

10:57AM 9 "I TOLD HIM CVS HAS BETTER FOOTPRINT IN SOCAL BUT

10:57AM 10 WALGREENS IS NOT TOO FAR BEHIND."

10:57AM 11 Q. NOW ON TO PAGE 8.

10:57AM 12 A. "CVS WON'T HAPPEN FOR ANOTHER YEAR."

10:57AM 13 "SO IF THEY WANT WE WILL MOVE WITHOUT THEM."

10:57AM 14 "WE WILL TALK ABOUT WAG WHEN U R BACK N."

10:57AM 15 "I SENT U CONTRACT AND COVER NOTE. PLEASE SPEND TIME ON

10:57AM 16 THAT SO I CAN SEND OUT."

10:57AM 17 Q. "HMM."

10:58AM 18 "YEAH."

10:58AM 19 "K."

10:58AM 20 "WHAT'S YOUR SENSE ON WHY 12 MO FOR SERVICE?"

10:58AM 21 "WHERE DID U LEAVE IT WITH HIM?"

10:58AM 22 A. "THEY DON'T KNOW THE UPSIDE OR DOWNSIDE OF NOT HAVING

10:58AM 23 THIS."

10:58AM 24 Q. "YEAH."

10:58AM 25 "WAS HE UPSET ABOUT MISSING PA?"

10:58AM 1 A. "AND THE FACT THAT WE ARE NOT GROWING WITH WAG IS
10:58AM 2 SOMETHING THAT THEY ARE TRYING TO UNDERSTAND."
10:58AM 3 "THEY ARE ALL LEMMINGS. THEY ONLY WANT IT IF OTHERS WANT
10:58AM 4 IT."
10:58AM 5 Q. "THINKING."
10:58AM 6 A. "THE MINUTE I SAID CALIFORNIA HIS QUESTION WAS WHY CVS,
10:58AM 7 WHY NOT WALGREENS?"
10:58AM 8 Q. "I KNOW."
10:58AM 9 A. "INSTEAD IF THERANOS WAS STRATEGIC TO THEM HE WOULD HAVE
10:58AM 10 JUMPED ON IT."
10:58AM 11 Q. "SEEING OUR LOCATIONS IN PA WILL BE THE SAME REACTION."
10:58AM 12 A. "THEY DON'T THINK OF US AS STRATEGIC. EVERY CONVERSATION
10:58AM 13 I HAVE WITH HIM HE SPEND AT LEAST HALF OF IT IN WHEN WE CAN PUT
10:58AM 14 DEVICES IN MINUTE CLINICS."
10:59AM 15 "JUST LIKE 3 YEARS AGO."
10:59AM 16 Q. NOW ON TO PAGE 9.
10:59AM 17 MS. HOLLIMAN, I THINK THAT'S PAGE 16. DO WE HAVE 9 NEXT?
10:59AM 18 THAT'S IT.
10:59AM 19 A. "HIGHEST VOLUME DAY TODAY .547 IN WAG."
10:59AM 20 Q. AND NOW ON TO PAGE 10.
10:59AM 21 A. "JC ARTICLE IS OUT."
10:59AM 22 Q. PAGE 11?
11:00AM 23 A. "I AM OK WITH LESS BLOOD AND DISCOMFORT IN HOLDING
11:00AM 24 STATEMENT."
11:00AM 25 Q. "ALMOST ODD IF NOT THERE."

11:00AM 1 AND NOW PAGE 12.

11:00AM 2 A. "OK."

11:00AM 3 "JUST WORRIED ABOUT FDA AND CMS."

11:00AM 4 "BUT OK."

11:00AM 5 "HAVE TO TAKE THIS RISK."

11:00AM 6 Q. "WE MADE SUCH BIG DEAL WHEN THEY WERE HERE ABOUT

11:00AM 7 VENIPUNCTURE BEING LESS BLOOD I AM COMFORTABLE WITH IT."

11:00AM 8 "CRAMER WANTS EXCLUSIVE."

11:00AM 9 "NO OTHER T.V."

11:00AM 10 A. "WAIT FOR DAVID."

11:01AM 11 Q. NOW ON TO PAGE 13.

11:01AM 12 "SENDING DRAFT RUPERT EMAIL. THE LANGUAGE ABOUT WHAT JC

11:01AM 13 SAID IS DAVID'S LANGUAGE DYING."

11:01AM 14 "FYI."

11:01AM 15 A. "OK."

11:01AM 16 "WHICH PART IS DAVID LANGUAGE."

11:01AM 17 Q. "THE PART ABOUT WHY I DIDN'T WANT TO TALK TO JC (HIS

11:01AM 18 ACCUSATIONS) AS WELL AS THE OTHER PARAGRAPHS THAT WEREN'T THERE

11:01AM 19 BEFORE. EVERYTHING NEW EXCEPT THE ONE SENTENCE I ADDED ON THE

11:01AM 20 NEW ARTICLE."

11:01AM 21 "I AM COMFORTABLE WITH SAYING THE DEATH AND SEX THING TO

11:01AM 22 RUPERT BC IT MAKES THE POINT."

11:01AM 23 A. "DON'T."

11:01AM 24 Q. "DON'T WHAT?"

11:01AM 25 A. "DON'T MAKE THE DEATH AND SEX POINT. NOT OK."

11:01AM 1 Q. "CHALLENGE IS YOU SAW HOW EVERYONE REACTED IN PRESS TO ME
11:01AM 2 NOT MEETING WITH HIM."
11:01AM 3 "THEY DIDN'T THINK HIM CHALLENGING ME ON PATENTS WAS
11:02AM 4 REMOTELY A GOOD REASON NOT TO MEET WITH HIM."
11:02AM 5 A. "BUT WE HAVE ENUFF POINTS TO SAY I DIDN'T MEET WITH HIM
11:02AM 6 BECAUSE OF HIS FALSE ACCUSATIONS AND DIDN'T HAVE TO MEET WITH
11:02AM 7 SOMEONE WHO WAS ATTACKING ME WITHOUT EVEN MEETING WITH ME. FOR
11:02AM 8 EXAMPLE PATENTS."
11:02AM 9 "I WOULDN'T OPEN UP USE PERSONAL LIFE OR MURDER BECAUSE
11:02AM 10 ENOUGH PEOPLE ON TWITTER WILL ASSUME THAT THERE IS SOMETHING
11:02AM 11 THERE.
11:02AM 12 "IT'S FILTH."
11:02AM 13 "AND WE NEED TO GET OUT OF FLIRTY."
11:02AM 14 "FILTH."
11:02AM 15 Q. "AGREE FOR SURE ON OUTSIDE WORLD. EVEN WHEN RUPERT TO
11:02AM 16 MAKE POINT."
11:02AM 17 A. "IF U FEEL STRONGLY ABOUT MURDER. BUT NOT PERSONAL LIFE."
11:02AM 18 "I THINK IT IS IMPORTANT TO SEND THIS EMAIL BUT DOESN'T
11:03AM 19 HELP WITH PUBLIC BEATING. ALL OUR PARTNERS ARE BAILING ONE AT
11:03AM 20 A TIME AND SAME WITH OUR INVESTORS."
11:03AM 21 Q. AND NOW ON TO PAGE 14.
11:03AM 22 A. "DIGNITY WAG EVERYONE IS POSTURING TO WALK AWAY. WE R
11:03AM 23 LOSING LEVERAGE FAST."
11:03AM 24 Q. "HAVE YOU TALKED TO WAG?"
11:03AM 25 A. "THEY ARE NOT TALKING FOR NOW UNTIL THEIR LAWYERS SAY SO."

11:03AM 1 Q. "TO US?"

11:03AM 2 A. "YES."

11:03AM 3 "AT C LEVEL."

11:03AM 4 Q. "THEIR LAWYERS TOLD THEM NOT TO TALK TO US?"

11:03AM 5 A. "YES."

11:03AM 6 Q. "WOW."

11:03AM 7 A. "IN SO MANY WORDS."

11:03AM 8 "NOT EXACTLY BUT THEY WILL BRING ALL OF THIS UP ABOUT

11:03AM 9 FINGERSTICK, ET CETERA, IN CONTRACT NEGOTIATIONS."

11:03AM 10 "IT IS GOING TO BE A VERY DIFFICULT 12 MONTHS."

11:04AM 11 "OUR CLIA LAB FAILED MPV PT AT ALL 5 LEVELS. JUST FOUND

11:04AM 12 OUT. DEALING WITH IT."

11:04AM 13 Q. NOW ON TO PAGE 15.

11:04AM 14 A. "MISS OLD DAYS. THESE DAYS ARE NOT WORTH WHATEVER WE R

11:04AM 15 TRYING TO DO HERE."

11:04AM 16 "NIM JUST TEXTED ME. WANTS TO TALK URGENTLY."

11:04AM 17 Q. "U CALLING HIM?"

11:04AM 18 A. "HE WILL CALL ME WHEN READY."

11:04AM 19 Q. "LET ME KNOW HOW IT GOES. THE FACTS ARE ON OUR SIDE."

11:04AM 20 A. "I KNOW. I AM STRONG ON FACTS. THEY ALWAYS REACT TO

11:04AM 21 ANYTHING BUT I WILL BE STRONG."

11:04AM 22 Q. AND FINALLY PAGE 16.

11:04AM 23 A. "OK. WAG FREAKING OUT. LACK OF TRANSPARENCY."

11:05AM 24 "WHY THEY FOUND THIS ALL OUT THRU MEDIA AND NOT THRU US."

11:05AM 25 Q. "K. THAT'S WHAT WE'LL DO."

11:05AM 1 "HOW WAS NIM?"

11:05AM 2 A. "WHY WE DIDN'T TELL THEM ABOUT TURNING OFF NANOTAINER A."

11:05AM 3 Q. "DID YOU TELL HIM IT LITERALLY JUST HAPPENED?"

11:05AM 4 A. "YES."

11:05AM 5 Q. "AND WE HADN'T FINALIZED PLAN W FDA YET AND STILL

11:05AM 6 HAVEN'T."

11:05AM 7 A. "I TOLD HIM WE WERE SURPRISED BY THE ARTICLE AS MUCH AS

11:05AM 8 THEY R."

11:05AM 9 "YES."

11:05AM 10 "BUT IT WAS MATTER OF COMMUNICATION. I HAD ACTUALLY

11:05AM 11 THOUGHT ABOUT IT BUT GOT TOO BUSY TO CHAT WITH U."

11:05AM 12 Q. "THEN LET'S SHOW THEM THAT THIS LITERALLY IS STILL UP IN

11:05AM 13 AIR."

11:05AM 14 "SO WE LITERALLY JUST DECIDED SINCE THE DISCUSSION IS

11:05AM 15 GETTING AIRED OUT IN PRESS?"

11:05AM 16 A. "OK."

11:05AM 17 "HOWEVER ISSUE IS WE DIDN'T TELL THEM IN ADVANCE ABOUT

11:05AM 18 SWITCHING."

11:05AM 19 Q. "WE'LL HAVE TO PRESENT WELL THAT WE HADN'T DECIDED TO."

11:06AM 20 A. "BAD IDEA. AT THIS POINT THEY KNOW. SO NEED TO BE

11:06AM 21 TRANSPARENT."

11:06AM 22 Q. "HOW LONG HAS IT BEEN THAT WE DIDN'T TELL THEM?"

11:06AM 23 A. "3-4 WEEKS."

11:06AM 24 Q. "I'M TRYING TO REMEMBER WHAT OUR THINKING WAS ON THAT."

11:06AM 25 A. "NONE. WE JUST DIDN'T TELL THEM THINKING UNDER NEW MODEL

11:06AM 1

THIS DOESN'T MATTER."

11:06AM 2

"BUT ATTACKS LIKE THIS SCARE THEM AS THEY SCARE EVERYONE."

11:06AM 3

Q. "YEAH."

11:06AM 4

MR. JHAVERI, WE JUST READ TEXT MESSAGES BETWEEN MARCH OF

11:06AM 5

2015 AND OCTOBER OF 2015.

11:06AM 6

DURING THIS PERIOD, WERE YOU WORKING DILIGENTLY TO

11:06AM 7

OPERATIONALIZE THERANOS BLOOD TESTING SERVICES INSIDE OF

11:06AM 8

WALGREENS STORES?

11:06AM 9

A. YES.

11:06AM 10

MR. SCHENK: YOUR HONOR, MAY I HAVE ONE MOMENT?

11:06AM 11

THE COURT: YES.

11:07AM 12

(DISCUSSION AMONGST GOVERNMENT COUNSEL OFF THE RECORD.)

11:07AM 13

MR. SCHENK: NO FURTHER QUESTIONS. THANK YOU.

11:07AM 14

THE COURT: ALL RIGHT. THANK YOU.

11:07AM 15

DO YOU HAVE CROSS-EXAMINATION?

11:07AM 16

MR. DOWNEY: I WILL, YOUR HONOR.

11:07AM 17

THE COURT: LET'S TAKE OUR MORNING RECESS NOW,

11:07AM 18

LADIES AND GENTLEMEN.

11:07AM 19

SHOULD WE TAKE 25 MINUTES? LET'S DO THAT. 25 MINUTES.

11:07AM 20

25 MINUTES.

11:07AM 21

YOU MAY STAND DOWN, SIR. YOU CAN STAND DOWN AND WE'LL

11:07AM 22

TAKE 25 MINUTES.

11:07AM 23

MR. SCHENK: THANK YOU.

11:07AM 24

(RECESS FROM 11:07 A.M. UNTIL 11:45 A.M.)

11:45AM 25

THE COURT: ALL RIGHT. THANK YOU. WE'RE BACK ON

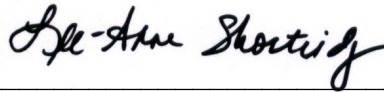
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: OCTOBER 14, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 27
)
ELIZABETH A. HOLMES,) NOVEMBER 3, 2021
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DEFENDANT.) PAGES 5187 - 5382
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BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
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BY: ADELAIDA HERNANDEZ

OFFICE OF THE U.S. ATTORNEY
BY: LAKISHA HOLLIMAN, PARALEGAL
MADDI WACHS, PARALEGAL

WILLIAMS & CONNOLLY
BY: TIMIKA ADAMS-SHERMAN, PARALEGAL

TBC
BY: BRIAN BENNETT, TECHNICIAN

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INDEX OF PROCEEDINGS

GOVERNMENT'S:

DANIEL MOSLEY

CROSS-EXAM BY MR. WADE (RES.)

P. 5217

REDIRECT EXAM BY MR. SCHENK

P. 5374

09:11AM 1 INDICATED ON PAGES 78 THROUGH 80, AND THE GOVERNMENT COULD HAVE
09:11AM 2 GIVEN NOTICE, AND/OR USING ANYTHING OUTSIDE OF THOSE 25 ASSAYS
09:11AM 3 FOR A DIFFERENT PURPOSE. THE COURT DIDN'T HAVE ANY PROBLEM
09:11AM 4 WITH THAT.

09:11AM 5 AND LET ME ALSO NOTE -- I THINK I NOTED, MR. BOSTIC, IN
09:11AM 6 YOUR PLEADINGS, YOUR SIDE'S PLEADINGS, YOU SUGGESTED THERE
09:12AM 7 WASN'T A HEARING ON THIS, AND I THINK THAT'S RIGHT. WE DIDN'T
09:12AM 8 DISCUSS THIS AT A FORMAL HEARING. THERE WASN'T ANY ORAL
09:12AM 9 ARGUMENT ON THIS AT THE HEARING.

09:12AM 10 BUT IF MY RECOLLECTION IS CORRECT, I THINK THIS IS ONE OF
09:12AM 11 THOSE THREE OR FOUR MILS THAT THE PARTIES COLLECTIVELY SAID NO
09:12AM 12 ARGUMENT WAS NECESSARY. I THINK THAT'S RIGHT. I THINK THIS
09:12AM 13 FELL IN THAT CATEGORY.

09:12AM 14 MS. TREFZ: YES, YOUR HONOR.

09:12AM 15 THE COURT: AND THAT'S WHY WE DIDN'T HAVE AN ORAL
09:12AM 16 ARGUMENT ON IT.

09:12AM 17 WE HAD MANY OTHER THINGS TO TALK ABOUT, AND WE DID TALK
09:12AM 18 ABOUT, BUT THIS WAS ONE OF THREE OR FOUR YOU SAID WE'RE FINE
09:12AM 19 WITH, SO I RECOGNIZE THAT.

09:12AM 20 ALL RIGHT. THANK YOU VERY MUCH FOR THIS.

09:12AM 21 LET ME JUST SAY, I'M GOING TO ISSUE A SHORT ORDER ON THIS.

09:12AM 22 I THINK IT'S APPROPRIATE TO GIVE YOU AN ORDER.

09:12AM 23 BUT, MR. BOSTIC, I'M TROUBLED BY THIS, AND THE COURT MAY

09:12AM 24 VERY WELL LIKELY GRANT THIS MOTION JUST BASED ON OUR

09:12AM 25 CONVERSATION HERE, AND THE COURT'S 798, AS WELL AS LOOKING BACK

09:12AM 1 AT 568, 711, 664 AND THE OTHER DOCUMENTS THAT WE HAVE
09:12AM 2 DISCUSSED. THAT IS THE HISTORY OF HOW WE GOT HERE.
09:13AM 3 SO I THINK I AM -- I THINK I OWE FIDELITY TO THE COURT'S
09:13AM 4 798, PAGES 78 THROUGH 80, IN THAT ANALYSIS HERE. BUT I'LL GET
09:13AM 5 A SHORT ORDER.
09:13AM 6 THIS WITNESS IS SCHEDULED FOR NEXT WEEK, I BELIEVE.
09:13AM 7 MR. BOSTIC: YOUR HONOR, THIS WITNESS WAS SCHEDULED
09:13AM 8 TO TESTIFY AS EARLY AS TOMORROW.
09:13AM 9 THE COURT: OH, DEAR.
09:13AM 10 MR. BOSTIC: HE IS IN TOWN, BUT CERTAINLY WE'RE
09:13AM 11 GUIDED BY THE COURT'S ORDER.
09:13AM 12 THE COURT: OKAY.
09:13AM 13 MR. BOSTIC: I'LL ONLY JUST EMPHASIZE MY POINT, I
09:13AM 14 THINK NOTICE TO THE DEFENSE SHOULD BE THE GUIDING PRINCIPLE
09:13AM 15 HERE, AND THE FACT THAT THERE WAS A MISUNDERSTANDING BEFORE --
09:13AM 16 I THINK, YOU KNOW, WITH RESPECT TO DEFENSE COUNSEL, I DON'T
09:13AM 17 THINK THE DEFENSE SHOULD BE REWARDED FOR SAVING THIS AS A TRAP
09:13AM 18 TO SPRING ON THE GOVERNMENT THE WEEK THAT THE WITNESS IS
09:13AM 19 PLANNING TO TESTIFY.
09:13AM 20 BUT WITH THAT I'LL SUBMIT.
09:13AM 21 THE COURT: ALL RIGHT. THANK YOU VERY MUCH. THANK
09:13AM 22 YOU.
09:13AM 23 MS. TREFZ: THANK YOU.
09:13AM 24 THE COURT: WELL, I'LL STEP DOWN AND THEN WE'LL
09:13AM 25 BRING OUR JURY IN.

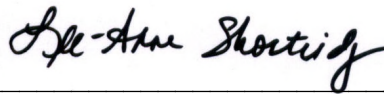
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 3, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 30
)
ELIZABETH A. HOLMES,) NOVEMBER 9, 2021
)
DEFENDANT.) PAGES 5671 - 5872
_____)

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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TBC
BY: BRIAN BENNETT, TECHNICIAN

INDEX OF PROCEEDINGS

GOVERNMENT'S:

LYNETTE SAWYER

CROSS-EXAM BY MR. WADE (RES.) P. 5730

REDIRECT EXAM BY MR. LEACH P. 5772

RE-CROSS-EXAM BY MR. WADE P. 5777

KINGSHUK DAS

DIRECT EXAM BY MR. LEACH P. 5781

CROSS-EXAM BY MR. WADE P. 5861

08:48AM 1 QUALITY SYSTEMS ISSUE.

08:48AM 2 AND WHEN SHE TALKS TO LISA PETERSON, SHE AGAIN MINIMIZES
08:48AM 3 THE EXTENT OF WHAT DR. DAS IS FINDING. THAT'S ONE WAY THAT IT
08:48AM 4 CONNECTS TO HER STATE OF MIND.

08:49AM 5 THE SECOND WAY IT CONNECTS IS THAT FOR ALL OF THE REASONS
08:49AM 6 THAT WE TALKED ABOUT WITH THE CMS REPORT, THAT THE DEFENDANT
08:49AM 7 HAS INJECTED EVIDENCE, AND THIS IS AT 7653 AND 1052 WHERE
08:49AM 8 DOCUMENTS HAVE BEEN OFFERED TO SHOW MS. HOLMES'S STATE OF MIND
08:49AM 9 IN 2016 GENERALLY ABOUT THE TECHNOLOGY.

08:49AM 10 AND THE FACT THAT THERANOS IS REQUIRED TO VOID THESE TESTS
08:49AM 11 IN THIS EXACT SAME TIME PERIOD GOES TO HER OVERALL KNOWLEDGE
08:49AM 12 AND STATE OF MIND, WHICH THE DEFENSE HAS PROFFERED AS RELEVANT.

08:49AM 13 SO 407 IS A RED HERRING IN THIS CASE. THEY WERE REQUIRED
08:49AM 14 TO DO THIS. DR. DAS WILL -- TO VOID THE TESTS. HE WILL SAY
08:49AM 15 THAT.

08:49AM 16 AND IT GOES DIRECTLY TO THE ACCURACY OF THE TESTS, AND IT
08:49AM 17 GOES DIRECTLY TO MS. HOLMES'S STATE OF MIND.

08:49AM 18 FOR THAT REASON IT SHOULD COME IN.

08:49AM 19 THE COURT: OKAY. DID YOU WANT TO SPEAK TO ANY OF
08:49AM 20 THE OTHER COMMENTS?

08:49AM 21 MR. LEACH: I DID, YOUR HONOR.

08:50AM 22 WITH RESPECT TO THE CONFRONTATION ISSUE, I DON'T THINK
08:50AM 23 THAT'S AN ISSUE. THE CMS REPORT IS NOT TESTIMONIAL, AND, YOU
08:50AM 24 KNOW, IT'S NOT PREPARED IN A LAW ENFORCEMENT CONTEXT, SO I
08:50AM 25 DON'T THINK THERE'S A CONFRONTATION ISSUE.

09:02AM 1 THAT THEY'RE GOING TO TRY TO OBTAIN TESTIMONY IN CONNECTION
09:02AM 2 WITH THAT WHEN THAT WAS NOT -- THAT IS NOT IN THIS RECORD, AND
09:02AM 3 OBVIOUSLY IT WOULD BE EXTREMELY PREJUDICIAL, AND IT WOULD
09:02AM 4 CLEARLY BE AN EXPERT OPINION IF, IF -- GIVEN THAT DOCTOR --
09:02AM 5 THIS WAS NOWHERE IN DR. DAS'S SPHERE OF INFLUENCE.

09:02AM 6 SO I WANTED TO RAISE -- THAT'S AN IMPORTANT ISSUE FOR THE
09:02AM 7 DEFENSE AND A NEW ISSUE, AND I WANTED TO RAISE THAT AS WELL.

09:02AM 8 THE COURT: OKAY.

09:03AM 9 MR. LEACH: IF I COULD RESPOND BRIEFLY, YOUR HONOR,
09:03AM 10 BECAUSE I THINK THERE ARE TWO VERY DIFFERENT ISSUES, AND I
09:03AM 11 THINK ON THAT SECOND ISSUE I MIGHT BE ABLE TO CLEAR UP SOME OF
09:03AM 12 THE DEFENSE'S CONCERN.

09:03AM 13 WITH RESPECT TO THE VOIDING, DR. DAS IS THE AUTHORITY ON
09:03AM 14 THIS. HE WAS THE LAB DIRECTOR AT THE TIME. AND 407 APPLIES TO
09:03AM 15 VOLUNTARY MEASURES WHERE A COMPANY ON ITS OWN IN A MATTER OF
09:03AM 16 BEING CONSERVATIVE DECIDES TO DO SOMETHING.

09:03AM 17 HERE UNDER SERIOUS THREAT OF REGULATORY PRESSURE FROM CMS,
09:03AM 18 DR. DAS CONCLUDED THAT THERE WERE ERRORS IN THE TESTS. ONCE HE
09:03AM 19 CONCLUDED THAT, AND I NOW HAVE THE RIGHT CITE, 493.1291,
09:03AM 20 REQUIRED HIM TO CORRECT THOSE REPORTS AND NOTIFY THE PATIENTS.

09:03AM 21 THE FACT THAT I CAN'T CORRECT THE REPORT TO SAY A VALUE IS
09:03AM 22 Y INSTEAD OF X AND INSTEAD WHOLESALE VOIDS IT IS NEITHER HERE
09:03AM 23 NOR THERE.

09:04AM 24 HE WILL NOT SAY THIS WAS OUT OF AN ABUNDANCE OF CAUTION.
09:04AM 25 HE WILL SAY I -- MY RESPONSIBILITIES AS THE CLIA LAB DIRECTOR

01:15PM 1 MY NAME IS KINGSHUK DAS. THAT IS SPELLED K-I-N-G-S-H-U-K.

01:15PM 2 LAST NAME DAS, D-A-S.

01:15PM 3 THE COURT: THANK YOU.

01:15PM 4 COUNSEL.

01:15PM 5 MR. LEACH: THANK YOU, YOUR HONOR.

01:15PM 6 **DIRECT EXAMINATION**

01:15PM 7 BY MR. LEACH:

01:15PM 8 Q. GOOD AFTERNOON, DR. DAS.

01:15PM 9 IN OR ABOUT DECEMBER OF 2015, WERE YOU ENGAGED TO SERVE AS

01:15PM 10 THE LABORATORY DIRECTOR OF THERANOS'S CALIFORNIA CLINICAL

01:15PM 11 LABORATORY?

01:15PM 12 A. YES, I WAS.

01:15PM 13 Q. OKAY. HOW LONG DID YOU SERVE IN THAT ROLE?

01:15PM 14 A. APPROXIMATELY TWO AND A HALF YEARS.

01:15PM 15 Q. OKAY. LET'S TALK A LITTLE BIT ABOUT YOUR EDUCATIONAL AND

01:15PM 16 PROFESSIONAL BACKGROUND.

01:15PM 17 DO YOU HAVE A COLLEGE DEGREE?

01:15PM 18 A. I DO.

01:15PM 19 Q. WHERE DID YOU GET YOUR COLLEGE DEGREE FROM?

01:15PM 20 A. AT CASE WESTERN RESERVE UNIVERSITY.

01:15PM 21 Q. AND WHAT WAS YOUR DEGREE IN?

01:15PM 22 A. IT WAS A BACHELOR OF ARTS IN BIOCHEMISTRY.

01:15PM 23 Q. AND WHEN DID YOU OBTAIN YOUR BACHELOR OF ARTS IN

01:15PM 24 BIOCHEMISTRY FROM CASE WESTERN?

01:15PM 25 A. THAT WOULD HAVE BEEN 1996.

01:15PM 1 Q. AND DO YOU HAVE A MEDICAL DEGREE?

01:16PM 2 A. I DO.

01:16PM 3 Q. AND IS THAT ALSO FROM CASE WESTERN RESERVE UNIVERSITY?

01:16PM 4 A. YES.

01:16PM 5 Q. AND WHEN DID YOU GET YOUR MEDICAL DEGREE?

01:16PM 6 A. THAT WOULD HAVE BEEN 2002.

01:16PM 7 Q. OKAY. AFTER OBTAINING YOUR MEDICAL DEGREE, DID YOU DO AN

01:16PM 8 INTERNSHIP?

01:16PM 9 A. I DID.

01:16PM 10 Q. AND WHAT WAS YOUR INTERNSHIP IN?

01:16PM 11 A. INTERNAL MEDICINE.

01:16PM 12 Q. AND WHERE DID YOU PERFORM YOUR INTERNSHIP?

01:16PM 13 A. THAT WAS AT THE UCLA WEST LOS ANGELES MEDICAL CENTER.

01:16PM 14 Q. IS THAT IN WESTWOOD?

01:16PM 15 A. YES, IT IS.

01:16PM 16 Q. OKAY. AND DID YOU PERFORM A RESIDENCY?

01:16PM 17 A. I DID.

01:16PM 18 Q. AND WHAT WAS YOUR RESIDENCY IN?

01:16PM 19 A. IN CLINICAL PATHOLOGY.

01:16PM 20 Q. WHAT IS CLINICAL PATHOLOGY?

01:16PM 21 A. THAT IS A DISCIPLINE OF PATHOLOGY THAT SPECIALIZES IN

01:16PM 22 LABORATORY MEDICINE.

01:16PM 23 Q. AFTER -- AND WHERE DID YOU PERFORM YOUR RESIDENCY?

01:16PM 24 A. IT WAS BETWEEN TWO SITES. FIRST AT WASHINGTON UNIVERSITY

01:16PM 25 IN ST. LOUIS, FOLLOWED BY THE UNIVERSITY OF SOUTHERN

01:16PM 1

CALIFORNIA.

01:16PM 2

Q. SO YOU WENT FROM UCLA TO U.S.C.?

01:16PM 3

A. THAT IS CORRECT, SIR.

01:17PM 4

Q. OKAY. AND DID YOU GO BACK TO UCLA AT SOME POINT AFTER

01:17PM 5

YOUR RESIDENCY?

01:17PM 6

A. I DID.

01:17PM 7

Q. TELL US ABOUT THAT, PLEASE.

01:17PM 8

A. I PURSUED A FELLOWSHIP IN MOLECULAR GENETICS AT UCLA.

01:17PM 9

Q. AND DID YOU ALSO SERVE ON THE FACULTY AT UCLA?

01:17PM 10

A. I DID AFTERWARD.

01:17PM 11

Q. AND WHAT POSITIONS ON THE FACULTY DID YOU HOLD?

01:17PM 12

A. I STARTED OFF AS AN ASSOCIATE MEDICAL DIRECTOR FOR THEIR

01:17PM 13

MOLECULAR PATHOLOGY DEPARTMENT, AND THAT WAS FOLLOWED BY A ROLE

01:17PM 14

AS DIRECTOR OF OPERATIONS OF GENETIC MEDICINE, AFTER WHICH I

01:17PM 15

WAS ASSOCIATE MEDICAL DIRECTOR OF CLINICAL LABORATORIES.

01:17PM 16

Q. OKAY. AND HAVE YOU SERVED IN SOMETHING CALLED UCLA

01:17PM 17

CLINICAL LABORATORIES?

01:17PM 18

A. YES.

01:17PM 19

Q. AND WHAT IS THAT?

01:17PM 20

A. THAT IS THE ACADEMIC MEDICAL CENTER LABORATORY AT UCLA.

01:17PM 21

Q. AND DID YOU HOLD A POSITION EQUIVALENT TO A LABORATORY

01:17PM 22

DIRECTOR IN THAT INSTITUTION?

01:17PM 23

A. CORRECT.

01:17PM 24

Q. ARE YOU LICENSED TO PRACTICE MEDICINE?

01:17PM 25

A. YES, I AM.

01:17PM 1 Q. IN WHAT STATES?

01:18PM 2 A. IN THE STATES OF CALIFORNIA AND MINNESOTA.

01:18PM 3 Q. AND DO YOU HOLD ANY BOARD CERTIFICATIONS?

01:18PM 4 A. I DO.

01:18PM 5 Q. IN WHAT?

01:18PM 6 A. IN CLINICAL PATHOLOGY.

01:18PM 7 Q. I WANT TO DRAW YOUR ATTENTION TO THE TIME PERIOD DECEMBER

01:18PM 8 OF 2015. IN OR ABOUT THAT TIME PERIOD, DID YOU LEARN OF A

01:18PM 9 COMPANY CALLED THERANOS?

01:18PM 10 A. I DID.

01:18PM 11 Q. OKAY. HOW DID THERANOS COME TO YOUR ATTENTION?

01:18PM 12 A. I RESPONDED TO A JOB POSTING ON THE THERANOS WEBSITE.

01:18PM 13 Q. AND WHAT WAS THE JOB POSTING FOR?

01:18PM 14 A. IT WAS FOR A LABORATORY DIRECTOR OF THEIR NEWARK,

01:18PM 15 CALIFORNIA LAB.

01:18PM 16 Q. AND DID YOU INTERVIEW FOR THAT POSITION?

01:18PM 17 A. I DID.

01:18PM 18 Q. AND DID YOU INTERVIEW WITH MS. HOLMES?

01:18PM 19 A. I DID.

01:18PM 20 Q. AND DID YOU ULTIMATELY GET THE JOB?

01:18PM 21 A. I DID.

01:18PM 22 Q. WHEN YOU WERE HIRED, WERE YOU ABLE TO START RIGHT AWAY IN

01:18PM 23 DECEMBER OF 2015?

01:18PM 24 A. NOT RIGHT AWAY.

01:18PM 25 Q. OKAY. WHY WAS THAT?

01:31PM 1 LATE 2015, EARLY 2016 TIME PERIOD?

01:31PM 2 A. THE NEWARK, CALIFORNIA LABORATORY WAS CONSIDERED HIGH

01:31PM 3 COMPLEXITY AND COULD OFFER SUCH TESTING.

01:31PM 4 Q. SUCH AS LDT'S?

01:31PM 5 A. SUCH AS LDT'S, YES.

01:31PM 6 Q. AND AS YOU'RE BECOMING THE LABORATORY DIRECTOR, DID YOU

01:31PM 7 DEVELOP A SENSE OF THE RELATIVE VOLUME OF TESTING BETWEEN THE

01:31PM 8 MODERATE COMPLEXITY LAB IN ARIZONA AND THE HIGH COMPLEXITY LAB

01:31PM 9 IN CALIFORNIA?

01:31PM 10 A. I DID NOT HAVE A GOOD SENSE OF THE PROPORTION OF TESTING

01:31PM 11 DONE IN BOTH LABS.

01:31PM 12 Q. AT SOME POINT DID YOU DEVELOP THAT UNDERSTANDING?

01:31PM 13 A. I DID NOT.

01:31PM 14 Q. OKAY. DID YOU HAVE ANY INTERACTIONS WITH SUNNY BALWANI?

01:31PM 15 A. YES, TO SOME EXTENT.

01:31PM 16 Q. OKAY. A LOT OF INTERACTIONS? A FEW INTERACTIONS?

01:32PM 17 DESCRIBE THOSE FOR US.

01:32PM 18 A. QUITE MINIMUM NUMBER OF INTERACTIONS. I BELIEVE SUNNY

01:32PM 19 LEFT THE COMPANY NOT TOO LONG AFTER I JOINED.

01:32PM 20 Q. SO SOMETIME IN THE MARCH 2016 TIME PERIOD?

01:32PM 21 A. YEAH. I'M NOT CLEAR ON THE EXACT DATES, BUT WE HAD VERY

01:32PM 22 LIMITED CHANCES TO INTERACT.

01:32PM 23 Q. LET'S MOVE FORWARD IN TIME TO THE TIME PERIOD OF MARCH OF

01:32PM 24 2016. THAT'S WHEN YOU BEGAN WORKING ON A FULL-TIME BASIS IN

01:32PM 25 THE LAB?

01:45PM 1
01:45PM 2
01:45PM 3
01:45PM 4
01:46PM 5
01:46PM 6
01:46PM 7
01:46PM 8
01:46PM 9
01:46PM 10
01:46PM 11
01:46PM 12
01:46PM 13
01:46PM 14
01:46PM 15
01:46PM 16
01:46PM 17
01:46PM 18
01:46PM 19
01:46PM 20
01:46PM 21
01:46PM 22
01:46PM 23
01:46PM 24
01:46PM 25

A. YES, I DO.

Q. THEN IT SAYS, "AS A RESULT OF THE SURVEY, IT WAS DETERMINED THAT YOUR FACILITY WAS NOT IN COMPLIANCE WITH ALL OF THE CONDITIONS REQUIRED FOR CERTIFICATION IN THE CLIA PROGRAM."

DO YOU SEE THAT?

A. I DO.

Q. AND IS "CONDITIONED" A TERM OF ART IN THE CLIA REGULATIONS?

A. YES, THAT IS.

Q. AND WHAT IS A CONDITION?

A. THESE ARE ANALOGOUS TO REQUIREMENTS OR REGULATIONS.

Q. OKAY. IT THEN SAYS, "IN ADDITION, BASED ON THE CONDITION-LEVEL REQUIREMENT, HEMATOLOGY, IT WAS DETERMINED THAT THE DEFICIENT PRACTICES OF THE LABORATORY POSE IMMEDIATE JEOPARDY TO PATIENT HEALTH AND SAFETY."

DO YOU SEE THAT?

A. YES, I DO.

Q. AND IS THAT PART OF WHAT WAS TRIGGERING THE URGENCY FOR YOUR RESPONSE TO CMS?

A. YES, THAT IS CORRECT.

Q. AND DID YOU HAVE DISCUSSIONS WITH MS. HOLMES ABOUT THE NEED TO RESPOND URGENTLY TO CMS?

A. YES, WE DID.

Q. FURTHER DOWN THERE'S A LIST OF CONDITIONS THAT WERE NOT MET.

02:12PM 1 Q. AND DID YOU UNDERSTAND TPS TO BE THE EDISON 3.5 DEVICE?

02:12PM 2 A. YES.

02:12PM 3 Q. AND WHAT DID YOU UNDERSTAND QUALITY ASSESSMENT TO MEAN?

02:12PM 4 A. MEANING THE TERM, MR. LEACH?

02:12PM 5 Q. YES.

02:12PM 6 A. THAT'S A TERM THAT ENCOMPASSES ALL QUALITY PROGRAMS, NOT
02:13PM 7 INCLUDING QUALITY CONTROL.

02:13PM 8 Q. AND WHAT DO YOU MEAN BY "QUALITY PROGRAMS"?

02:13PM 9 A. IN GENERAL, QUALITY CONTROL HAS TO DO WITH DAY-TO-DAY
02:13PM 10 RUNS, QUALITY OF DAY-TO-DAY RUNS.

02:13PM 11 AND QUALITY ASSESSMENT IS -- DESCRIBES ALL OF THE OTHER
02:13PM 12 QUALITY ACTIVITIES OUTSIDE OF THE DAY-TO-DAY RUNS ON ANY GIVEN
02:13PM 13 INSTRUMENT.

02:13PM 14 Q. AND WAS PART OF YOUR JOB AS THE LAB DIRECTOR TO
02:13PM 15 INVESTIGATE THIS FINDING, UNDERSTAND IT, AND COME UP WITH THE
02:13PM 16 COMPANY'S RESPONSE?

02:13PM 17 A. YES.

02:13PM 18 Q. IF WE CAN GO FURTHER DOWN, PLEASE, MS. HOLLIMAN, ON
02:13PM 19 PAGE 55.

02:13PM 20 IT READS HERE, "MONTHLY QC REPORTS WERE REVIEWED FOR
02:13PM 21 JULY 2014, OCTOBER 2014, AND FEBRUARY THROUGH JUNE 2015."

02:13PM 22 DID YOU ALSO REVIEW MONTHLY QC REPORTS IN THE COURSE OF
02:14PM 23 YOUR WORK AS THE LABORATORY DIRECTOR?

02:14PM 24 A. WE DID. WE HAD THE REPORTS CREATED FOR US.

02:14PM 25 Q. OKAY. AND THAT WAS IN PART TO RESPOND TO THE 2567?

02:14PM 1 A. THAT'S CORRECT.

02:14PM 2 Q. AND IN NUMBER 2 IT SAYS, "THE TOTAL PERCENTAGE OF QC
02:14PM 3 VALUES GREATER THAN 2 STANDARD DEVIATIONS (SDS) WAS REVIEWED BY
02:14PM 4 THE SURVEYOR."

02:14PM 5 DO YOU SEE THAT LANGUAGE?

02:14PM 6 A. I DO.

02:14PM 7 Q. AND DO YOU UNDERSTAND WHAT IS MEANT BY "STANDARD
02:14PM 8 DEVIATIONS"?

02:14PM 9 A. YES, I DO.

02:14PM 10 Q. AND WHAT IS A STANDARD DEVIATION?

02:14PM 11 A. WOULD YOU LIKE THE MORE TECHNICAL DEFINITION?

02:14PM 12 Q. I'D LIKE THE LESS TECHNICAL DEFINITION IF YOU COULD.

02:14PM 13 A. IT'S, IN GENERAL, AN ESTIMATE OF THE SPREAD OF A DATA SET,
02:14PM 14 HOW WIDELY THE VALUES VARY.

02:14PM 15 Q. OKAY.

02:14PM 16 A. IN LABORATORY PARLANCE, WE USE IT TO ESTIMATE PRECISION.

02:14PM 17 Q. AND IF WE CAN GO TO THE NEXT PAGE, PLEASE, PAGE 56.

02:15PM 18 DR. DAS, DO SOME OF THE CMS FINDINGS CONTINUE -- WITH
02:15PM 19 RESPECT TO THIS D TAG CONTINUE ON TO THE NEXT PAGE?

02:15PM 20 A. YES, I SEE THAT.

02:15PM 21 Q. OKAY. DO YOU SEE WHERE IT SAYS, "IN JULY 2014, THE DATA
02:15PM 22 REVEALED THE FOLLOWING TESTS SHOWED PERCENTAGE OF QC SAMPLES
02:15PM 23 WITH MORE THAN 15 PERCENT OF VALUES GREATER THAN 2 SD." AND
02:15PM 24 THEN THERE'S TESTOSTERONE, TOTAL T4, VITAMIN D.

02:15PM 25 "OVERALL 16 PERCENT OF QC SAMPLES ON ALL TESTS ON ALL

02:15PM 1 DEVICES HAD VALUES GREATER THAN 2 SDS."

02:15PM 2 DO YOU SEE THAT LANGUAGE?

02:15PM 3 A. I DO SEE THAT.

02:15PM 4 Q. OKAY. AND WERE TST, TOTAL T4, AND VITAMIN D ASSAYS RUN ON
02:15PM 5 THE EDISON IN THE 2014 TIME PERIOD?

02:15PM 6 A. THAT IS CORRECT. I BELIEVE THAT'S WHAT THEY'RE REFERRING
02:15PM 7 TO.

02:15PM 8 Q. AND DID YOU AND YOUR TEAM ALSO REVIEW THE DATA THAT IS
02:16PM 9 LISTED HERE ON THIS FORM?

02:16PM 10 A. YES.

02:16PM 11 Q. AND DID YOU REVIEW AN EVEN BROADER UNIVERSE OF QC DATA IN
02:16PM 12 ORDER TO RESPOND TO THE CMS REPORT?

02:16PM 13 A. WE DID.

02:16PM 14 Q. AND IS THIS -- IS THE FINDING LISTED HERE CONSISTENT WITH
02:16PM 15 WHAT YOU REVIEWED IN YOUR REVIEW OF DATA?

02:16PM 16 MR. WADE: YOUR HONOR, 702 ON THIS ISSUE,
02:16PM 17 PARTICULARLY GIVEN THE PURPOSE THAT THIS EVIDENCE HAS BEEN
02:16PM 18 OFFERED.

02:16PM 19 THE COURT: MR. LEACH, I THINK YOU'RE ON THE MARGINS
02:16PM 20 OF A 702 AREA, SO LET ME ASK YOU TO REPHRASE YOUR QUESTION.
02:16PM 21 BY MR. LEACH:

02:16PM 22 Q. DID YOU ALSO -- DID YOU ALSO REVIEW THE DATA THAT IS
02:16PM 23 LISTED IN THIS REPORT, IN THIS PARAGRAPH E, DR. DAS?

02:16PM 24 A. I DON'T RECALL THESE EXACT NUMBERS, BUT THESE TIME FRAMES
02:17PM 25 ARE CONSISTENT WITH MY RECOLLECTION.

02:17PM 1 Q. OKAY. AND IN RESPONDING TO CMS, DID -- OR YOU NEEDED TO
02:17PM 2 FORMULATE A RESPONSE TO CMS ON BEHALF OF THE COMPANY; IS THAT
02:17PM 3 CORRECT?

02:17PM 4 A. YES, THAT IS CORRECT.

02:17PM 5 Q. AND DID YOU LOOK AT NOT JUST DATA FOR JULY OF 2014, BUT A
02:17PM 6 BROADER UNIVERSE OF DATA IN ORDER TO UNDERSTAND AND RESPOND TO
02:17PM 7 CMS?

02:17PM 8 A. YES, WE DID.

02:17PM 9 Q. OKAY. AT ANY POINT DID YOU TELL CMS THAT THE COMPANY
02:17PM 10 DISAGREED WITH THIS PARTICULAR FINDING?

02:17PM 11 A. NO, I DON'T BELIEVE WE DID.

02:17PM 12 Q. OKAY. WHY NOT?

02:17PM 13 A. THESE FINDINGS --

02:17PM 14 MR. WADE: YOUR HONOR, AGAIN, 702. WE'RE JUST USING
02:17PM 15 REVERSE INSTEAD OF FORWARD.

02:17PM 16 THE COURT: I UNDERSTAND.

02:17PM 17 I THINK YOU'RE ASKING FOR AN OPINION THAT FALLS UNDER 702
02:17PM 18 THE WAY THE QUESTION IS FORMED, SO I'LL SUSTAIN THE OBJECTION.
02:17PM 19 BY MR. LEACH:

02:17PM 20 Q. BUT YOU NEVER SAID TO ANYBODY AT CMS, "I DISAGREE WITH
02:17PM 21 THIS FINDING"?

02:18PM 22 A. I DON'T RECALL SAYING THAT OR WRITING THAT.

02:18PM 23 Q. LET'S GO TO NUMBER F.

02:18PM 24 A. OKAY.

02:18PM 25 Q. AND IF WE CAN ENLARGE THAT, MS. HOLLIMAN.

02:18PM 1 I'M SORRY. I THINK WE'RE DOWN ON H. I WANTED TO FOCUS ON
02:18PM 2 F IF WE COULD:

02:18PM 3 THIS READS, DR. DAS, "IN OCTOBER 2014 THE DATA REVEALED
02:18PM 4 THE FOLLOWING TESTS SHOWED PERCENTAGE OF QC SAMPLES WITH MORE
02:18PM 5 THAN 15 PERCENT OF VALUES GREATER THAN 2 SD."

02:18PM 6 DO YOU SEE THAT LANGUAGE?

02:18PM 7 A. I DO.

02:18PM 8 Q. AND THEN THERE'S A LIST FOR ESTRADIOL, FREE T4, PROLACTIN,
02:18PM 9 SHBG, TSH, TST, TOTAL T3, TT4, VITAMIN D, AND VITAMIN B12.

02:19PM 10 DO YOU SEE THOSE?

02:19PM 11 A. I DO.

02:19PM 12 Q. AND ARE ALL OF THOSE ASSAYS THAT WERE RUN ON THE EDISON?

02:19PM 13 A. YES.

02:19PM 14 Q. AND AS A LAB DIRECTOR, IS IT DESIRABLE OR UNDESIRABLE TO
02:19PM 15 HAVE A CV OF GREATER THAN 15 PERCENT?

02:19PM 16 A. THAT WOULD BE UNDESIRABLE.

02:19PM 17 Q. THIS SAYS, "OVERALL 29 PERCENT OF QC SAMPLES ON ALL TESTS
02:19PM 18 ON ALL DEVICES HAD VALUES GREATER THAN 2 SD'S."

02:19PM 19 DO YOU SEE THAT?

02:19PM 20 A. YES, I SEE THAT.

02:19PM 21 Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?

02:19PM 22 A. THAT -- I UNDERSTAND THAT TO MEAN THAT 15 PERCENT OF THE
02:19PM 23 VALUES WERE VIOLATING THE 2 SD RULE, WHICH IS A COMMON QUALITY
02:19PM 24 CONTROL RULE.

02:19PM 25 Q. AND DID YOU HAVE DISCUSSIONS WITH MS. HOLMES ABOUT THIS

02:22PM 1 Q. OKAY. AND IN CONNECTION WITH YOUR REVIEW OF THE CMS
02:22PM 2 REPORT AND RESPONDING TO CMS, DID YOU HAVE DISCUSSIONS WITH
02:22PM 3 MS. HOLMES ABOUT WHAT CMS WAS FINDING WITH RESPECT TO CMS AND
02:23PM 4 WHAT YOU WERE FINDING AND WHAT THAT -- HOW TO RESPOND TO THAT?
02:23PM 5 A. I COULD USE A LITTLE MORE SPECIFICITY, MR. LEACH, IF YOU
02:23PM 6 MAY.
02:23PM 7 Q. THAT WAS A COMPOUND QUESTION. LET ME ASK IT BETTER.
02:23PM 8 IN THIS 2015 OR 2016, MARCH AND APRIL TIME PERIOD, DID YOU
02:23PM 9 HAVE DISCUSSIONS WITH MS. HOLMES ABOUT THE COMPANY'S PSA TEST?
02:23PM 10 A. I DID.
02:23PM 11 Q. AND WAS THAT IN THE CONTEXT OF SOME OF THE CMS FINDINGS
02:23PM 12 AND HOW TO RESPOND TO THAT?
02:23PM 13 A. IT WAS RELATED TO THE CMS FINDINGS.
02:23PM 14 Q. OKAY. DESCRIBE TO US YOUR CONVERSATIONS WITH MS. HOLMES?
02:23PM 15 A. I RECALL USING THE PSA TEST AS AN EXAMPLE OF THE EDISON'S
02:23PM 16 ERROR PROPENSITY OR GENERATING ERROR -- ERRONEOUS RESULTS.
02:23PM 17 Q. OKAY. AND DID YOU GIVE MS. HOLMES A PARTICULAR REASON WHY
02:23PM 18 YOU THOUGHT THE EDISON WAS PRONE TO ERRONEOUS RESULTS?
02:23PM 19 A. YES. IN REVIEWING THE DATA, IT ENDED UP BEING AN EASILY
02:24PM 20 DIGESTIBLE EXAMPLE OF THE EDISON'S ERRORS AND THAT I RECALL
02:24PM 21 QUITE A FEW FEMALE PATIENTS RETURNING PSA RESULTS, WHICH WOULD
02:24PM 22 BE HIGHLY UNLIKELY.
02:24PM 23 Q. WHY WAS THAT A RED FLAG TO YOU?
02:24PM 24 A. BECAUSE FEMALES SHOULD GENERALLY NOT HAVE PSA DETECTABLE.
02:24PM 25 IT SHOULD ONLY BE DETECTED IN MALES.

02:24PM 1 Q. AND WHY WERE YOU BRINGING THIS TO MS. HOLMES'S ATTENTION?

02:24PM 2 A. IT WAS JUST TO EXEMPLIFY WHAT WE WERE DISCUSSING REGARDING

02:24PM 3 SOME OF THE ERRORS SEEN ON THE TSPU.

02:24PM 4 Q. AND AFTER THIS CONVERSATION WITH MS. HOLMES, DID SHE COME

02:24PM 5 BACK TO YOU ABOUT WITH ANY LITERATURE RELATING TO PSA RESULTS?

02:24PM 6 A. YES, I BELIEVE SO. SHE OFFERED AN ALTERNATIVE

02:24PM 7 EXPLANATION.

02:24PM 8 Q. AND WHAT WAS THE ALTERNATIVE EXPLANATION?

02:24PM 9 A. I DON'T REMEMBER THE DETAILS, BUT IT WAS ALONG THE LINES

02:24PM 10 OF AN ARTICLE OR TWO DESCRIBING A FEW, I BELIEVE IT WAS A

02:25PM 11 FRACTION OF A SUBSET OF A RARE BREAST CANCER AND THOUGH FEMALES

02:25PM 12 FROM TIME TO TIME EXHIBITING PSA RESULTS FROM THEIR TUMORS.

02:25PM 13 Q. AND WAS THAT EXPLANATION SATISFYING TO YOU?

02:25PM 14 A. IT SEEMED IMPLAUSIBLE.

02:25PM 15 Q. LET ME MOVE FORWARD IN TIME, PLEASE, TO THE END OF OR THE

02:25PM 16 LATE TIME PERIOD OF MARCH OF 2016.

02:25PM 17 HAVING REVIEWED THE FORM 2567, DID YOU WRITE BACK TO CMS

02:25PM 18 WITH THE COMPANY'S RESPONSES?

02:25PM 19 A. YES, I DO RECALL THAT.

02:25PM 20 Q. OKAY. AND DID YOU -- YOU MENTIONED SOMETHING EARLIER

02:25PM 21 CALLED A PATIENT IMPACT ASSESSMENT.

02:25PM 22 WHAT IS THAT?

02:25PM 23 A. YES. THOSE WERE DESCRIPTIONS OF OUR ASSESSMENTS ON OUR

02:25PM 24 EVALUATION OF WHETHER THESE TESTS LED TO POTENTIAL FOR PATIENT

02:25PM 25 HARM.

02:25PM 1 Q. AND IN THE COURSE OF, IN THE COURSE OF PREPARING THESE

02:26PM 2 PATIENT IMPACT ASSESSMENTS, WERE YOU -- DID YOU VIEW YOURSELF

02:26PM 3 AS FULFILLING YOUR OBLIGATIONS AS THE CLIA LAB DIRECTOR?

02:26PM 4 A. YES, I DID.

02:26PM 5 Q. AND WHY DID YOU FEEL THAT WAS PART OF YOUR OBLIGATIONS AS

02:26PM 6 THE CLIA LAB DIRECTOR?

02:26PM 7 A. THAT'S NOT ONLY A REGULATORY OBLIGATION BUT A PROFESSIONAL

02:26PM 8 ONE AND AN ETHICAL ONE AS WELL.

02:26PM 9 Q. OKAY. LET ME DRAW YOUR ATTENTION BACK TO 7603,

02:27PM 10 SPECIFICALLY PAGES 82 AND 83.

02:27PM 11 DO YOU HAVE THAT IN FRONT OF YOU, DR. DAS?

02:27PM 12 A. YES, I DO. THANK YOU.

02:27PM 13 Q. OKAY. AND ON PAGE 82 THERE'S A CFR SECTION 493.1291,

02:27PM 14 STANDARD TEST REPORT.

02:27PM 15 DO YOU SEE THAT?

02:27PM 16 A. YES, I SEE THAT.

02:27PM 17 Q. AND IF YOU LOOK ON PAGE 83, THERE'S A SUBPARAGRAPH K.

02:27PM 18 DO YOU SEE WHERE IT SAYS, "WHEN ERRORS IN THE REPORTED

02:27PM 19 PATIENT TEST RESULTS ARE DETECTED, THE LABORATORY MUST DO THE

02:27PM 20 FOLLOWING"?

02:27PM 21 A. I DO SEE THAT.

02:27PM 22 Q. OKAY. AND DOES THAT LAY OUT CERTAIN THINGS THAT YOU FELT

02:27PM 23 AS THE LABORATORY DIRECTOR NEEDED TO BE DONE IF THE CONDITION

02:27PM 24 IN K WAS SATISFIED?

02:27PM 25 A. THAT'S CORRECT, THAT'S STANDARD PRACTICE.

02:27PM 1 Q. OKAY. IN THE COURSE OF RESPONDING TO THE CMS 2567, DID

02:28PM 2 YOU, AS THE LABORATORY, DETECT ERRORS IN THE PATIENT REPORTED

02:28PM 3 TEST RESULTS?

02:28PM 4 A. WE DID.

02:28PM 5 Q. AND DID YOU FEEL THAT YOU WERE REQUIRED TO TAKE CERTAIN

02:28PM 6 ACTION PURSUANT TO THIS CLIA REGULATION AND YOUR PROFESSIONAL

02:28PM 7 RESPONSIBILITIES?

02:28PM 8 A. YES, THAT'S CORRECT.

02:28PM 9 Q. LET ME DRAW YOUR ATTENTION, PLEASE, TO EXHIBIT 4943.

02:28PM 10 DO YOU HAVE THAT IN FRONT OF YOU, DR. DAS?

02:28PM 11 A. YES, I DO.

02:28PM 12 Q. DO YOU RECOGNIZE THE FIRST PAGE OF 4943?

02:28PM 13 A. I DO IN GENERAL, NOT THE SPECIFIC PAGE, THOUGH.

02:28PM 14 Q. OKAY. IN GENERAL, WHAT IS THIS?

02:28PM 15 A. IT LOOKS LIKE IT'S A TABLE OF CONTENTS FOR THE EXHIBITS

02:29PM 16 THAT WE SUBMITTED TO CMS AS EVIDENCE.

02:29PM 17 Q. AS PART OF YOUR REVIEW AND RESPONSE TO THE 2567?

02:29PM 18 A. THAT'S CORRECT.

02:29PM 19 Q. OKAY. DO YOU SEE THAT THERE'S A ROW -- THE THIRD ROW FROM

02:29PM 20 THE BOTTOM WITH TAB NUMBER 3?

02:29PM 21 A. YES, I DO.

02:29PM 22 Q. OKAY. AND WE CAN NOW TURN TO PAGE 9.

02:29PM 23 DO YOU SEE THE HEADING PATIENT IMPACT ASSESSMENT?

02:29PM 24 A. I DO. THE PRINT IS RATHER SMALL.

02:29PM 25 Q. OKAY. WE'LL, WE'LL --

02:29PM 1 A. WE'LL MANAGE.

02:29PM 2 Q. AND IS THIS A PATIENT IMPACT ASSESSMENT THAT WAS PROVIDED
02:29PM 3 TO CMS FOLLOWING YOUR REVIEW OF THE 2567?

02:29PM 4 A. I'LL NEED JUST A MOMENT TO REVIEW IT.

02:30PM 5 Q. YES. THANK YOU.

02:30PM 6 (PAUSE IN PROCEEDINGS.)

02:30PM 7 THE WITNESS: YES, I BELIEVE SO.

02:30PM 8 MR. LEACH: YOUR HONOR, I OFFER PAGE 1 AND 9 OF
02:30PM 9 4943.

02:30PM 10 (PAUSE IN PROCEEDINGS.)

02:30PM 11 MR. WADE: JUST THE SAME OBJECTIONS, YOUR HONOR.

02:30PM 12 THE COURT: ALL RIGHT. THANK YOU.

02:30PM 13 THE COURT WILL OVERRULE THE OBJECTION. THE FOUNDATION HAS
02:31PM 14 BEEN LAID. I THINK THERE WAS A PREVIOUS 407 OBJECTION THAT WAS
02:31PM 15 MADE, AND THAT IS OVERRULED NOW BY THE TESTIMONY OF THE
02:31PM 16 WITNESS. THE OBJECTION IS OVERRULED.

02:31PM 17 (GOVERNMENT'S EXHIBIT 4943, PAGES 1 AND 9, WAS RECEIVED IN
02:31PM 18 EVIDENCE.)

02:31PM 19 MR. LEACH: THANK YOU, YOUR HONOR. MAY WE DISPLAY,
02:31PM 20 YOUR HONOR?

02:31PM 21 THE COURT: YES.

02:31PM 22 BY MR. LEACH:

02:31PM 23 Q. JUST TO ORIENT THE JURY, DR. DAS, I WAS REFERENCING -- YOU
02:31PM 24 BELIEVE THIS WAS A DOCUMENT THAT WAS SUBMITTED TO CMS?

02:31PM 25 A. YES, I BELIEVE SO.

02:32PM 1 A. THOSE APPEAR TO BE THE SPECIFIC D TAGS REFERENCED IN THIS
02:33PM 2 PATIENT IMPACT ASSESSMENT.

02:33PM 3 Q. AND THOSE D TAGS ORIGINATE FROM THE 2567?

02:33PM 4 A. THAT'S CORRECT.

02:33PM 5 Q. AND EARLIER WE WERE LOOKING AT A D TAG FOR 2571, FINDING
02:33PM 6 NUMBER 3?

02:33PM 7 A. I BELIEVE WE WERE.

02:33PM 8 Q. AND SO DO YOU BELIEVE THAT THIS PATIENT IMPACT ASSESSMENT
02:33PM 9 RELATES TO THE PORTION OF THE CMS REPORT THAT WE JUST LOOKED
02:33PM 10 AT?

02:33PM 11 A. I EXPECT SO.

02:33PM 12 Q. OKAY. THIS SAYS, "THE LABORATORY AGREES THAT ITS
02:33PM 13 DESCRIPTION OF PRIOR ANALYSIS WERE LACKING SUFFICIENT DETAIL TO
02:33PM 14 EXPLAIN THE CONCLUSIONS SUBMITTED IN THE RESPONSE."

02:33PM 15 IS THAT A REFERENCE TO PRIOR RESPONSES THAT THERANOS HAD
02:33PM 16 MADE TO CMS?

02:33PM 17 A. I BELIEVE SO.

02:33PM 18 Q. IT THEN READS, "UPON A REVIEW OF THAT RESPONSE, INCLUDING
02:33PM 19 THE ENTIRETY OF THE PRIOR ANALYSIS OF TPS 3.5 QC DATA AND
02:33PM 20 PATIENT TEST RESULT DISTRIBUTIONS FOR ALL ANALYTES DURING THE
02:34PM 21 TIME PERIOD EXAMINED, THE LABORATORY MADE NOTE OF POOR QC
02:34PM 22 PERFORMANCE THROUGHOUT."

02:34PM 23 IS THAT AN ACCURATE STATEMENT?

02:34PM 24 A. THAT IS AN ACCURATE STATEMENT.

02:34PM 25 Q. AND THE PATIENT TEST RESULT DISTRIBUTIONS THAT YOU'RE

02:34PM 1 TALKING ABOUT THERE, DID THAT REFER TO ALL TESTS RUN ON THE
02:34PM 2 EDISON DEVICE?

02:34PM 3 A. YES, ALL TESTS.

02:34PM 4 Q. OKAY. AND DO YOU HAVE A MEMORY OF HOW MANY TESTS WERE RUN
02:34PM 5 ON THE EDISON DEVICE?

02:34PM 6 A. I BELIEVE IT WAS A TOTAL OF 12.

02:34PM 7 Q. OKAY. TWELVE TESTS RUN ON THE EDISON DEVICE THROUGHOUT
02:34PM 8 THE LIFE OF THE CLIA LAB?

02:34PM 9 A. THAT IS MY UNDERSTANDING.

02:34PM 10 Q. IT THEN SAYS, "THEREFORE, LABORATORY CONDUCTED AN EXPANDED
02:34PM 11 RETROSPECTIVE ANALYSIS FOR 2014 AND 2015 QC DATA."

02:34PM 12 WHAT DOES THAT MEAN?

02:34PM 13 A. IN GENERAL THAT MEANS WE EXPAND THE RANGE OF THE QC DATA
02:34PM 14 THAT WE LOOKED AT BECAUSE WE IDENTIFIED ISSUES WITH THE
02:34PM 15 ORIGINAL DATA, MEANING WE WANTED TO SEE HOW FAR THE POOR
02:35PM 16 PERFORMANCE EXTENDED.

02:35PM 17 Q. YOU WANTED TO LOOK AT A BROADER UNIVERSE?

02:35PM 18 A. YES, THAT'S ONE WAY TO DESCRIBE IT.

02:35PM 19 Q. OKAY. AND THAT'S WHAT YOU'RE REPORTING TO CMS?

02:35PM 20 A. YES, THAT'S CORRECT.

02:35PM 21 Q. OKAY. AFTER EXTENSIVE DIALOGUE WITH MS. HOLMES?

02:35PM 22 A. I DON'T KNOW HOW TO DESCRIBE.

02:35PM 23 Q. HOW ABOUT AFTER SOME DIALOGUE WITH MS. HOLMES?

02:35PM 24 A. YES, SOME DIALOGUE.

02:35PM 25 Q. IT THEN SAYS, "THE LABORATORY NOTED MULTIPLE AND RECURRENT"

02:35PM 1 TIME PERIODS (ACROSS ALL ANALYTES TESTED) OF ABRUPT SHIFTS IN
02:35PM 2 QC TARGET MEANS."
02:35PM 3 WHAT DOES THAT MEAN?
02:35PM 4 A. PLEASE GIVE A MINUTE TO REVIEW THAT.
02:35PM 5 (PAUSE IN PROCEEDINGS.)
02:35PM 6 THE WITNESS: SO THAT FIRST PART MEANS THAT THE
02:35PM 7 AVERAGE VALUES OF QUALITY CONTROL, THE TARGETS THAT WE WERE
02:36PM 8 TRYING TO REACH, OR THAT THE LABORATORY WAS TARGETING, WERE
02:36PM 9 BEING SHIFTED UNEXPLAINEDLY.
02:36PM 10 BY MR. LEACH:
02:36PM 11 Q. "HIGH RATES OF 1-2S QC RULE FAILURES."
02:36PM 12 WHAT IS MEANT BY "1-2S"?
02:36PM 13 A. SO THIS 1-2S ACTUALLY REFERS TO THE SAME QC RULE FAILURES
02:36PM 14 THAT THE CMS INSPECTORS WERE NOTING IN THAT D TAG. I BELIEVE
02:36PM 15 IT WAS 5791, I BELIEVE. SO THEY CALL IT A --
02:36PM 16 Q. AND THE 1-2S, THAT'S STANDARD DEVIATIONS?
02:36PM 17 A. YES. SO THE 2S REFERS TO 2 SD ANALOGOUS TO WHAT IS BEING
02:36PM 18 REFERRED TO IN THE D TAG.
02:36PM 19 Q. AND "QC CV'S FAR EXCEEDING LIMITS FOR A STABLE TESTING
02:36PM 20 PROCESS."
02:36PM 21 WHAT DID THAT MEAN?
02:36PM 22 A. TO SIMPLIFY THAT ONE A BIT, IT JUST MEANS THAT THERE WAS A
02:37PM 23 LOT OF IMPRECISION NOTED.
02:37PM 24 Q. AND IS IMPRECISION DESIRABLE OR UNDESIRABLE?
02:37PM 25 A. UNDESIRABLE.

02:37PM 1 Q. LET'S ZOOM OUT, MS. HOLLIMAN, AND LOOK AT THE NEXT TWO
02:37PM 2 PARAGRAPHS IN THIS PATIENT IMPACT ASSESSMENT.
02:37PM 3 DO YOU SEE WHERE IT SAYS PATIENT IMPACT, DR. DAS?
02:37PM 4 A. YES, I DO.
02:37PM 5 Q. AND THIS READS, "ALTHOUGH THE MAGNITUDE OF QC DEVIATIONS
02:37PM 6 FROM TARGET MEANS DOES NOT NECESSARILY REFLECT THE EXACT NATURE
02:37PM 7 AND MAGNITUDE OF BIAS ON PATIENT RESULTS BECAUSE OF DIFFERENCES
02:37PM 8 IN MATRICES, THE QC FAILURES IDENTIFIED BY THIS COMPREHENSIVE
02:37PM 9 RETROSPECTIVE ANALYSIS REFLECT A GLOBAL AND LONG-TERM FAILURE
02:37PM 10 OF THE QUALITY CONTROL PROGRAM FOR THIS INSTRUMENT, AS WELL AS
02:37PM 11 FAILURES OF RELATED QUALITY ASSURANCE PROCEDURES THAT SHOULD
02:37PM 12 HAVE ALERTED THE LABORATORY TO CORRECT SUCH AN UNSTABLE
02:37PM 13 PROCESS."
02:37PM 14 WHY DID YOU INCLUDE THIS IN THE PATIENT IMPACT PORTION OF
02:38PM 15 THIS?
02:38PM 16 A. FIRST OF ALL, THAT'S QUITE A MOUTHFUL.
02:38PM 17 Q. YES.
02:38PM 18 A. THIS WAS JUST TO DESCRIBE OUR FINDINGS.
02:38PM 19 Q. AND "THE LABORATORY HAS CONCLUDED THAT THERE IS A POSSIBLE
02:38PM 20 PATIENT IMPACT FOR EVERY TEST REPORTED FROM THE LABORATORY'S
02:38PM 21 TPS 3.5 INSTRUMENTS."
02:38PM 22 IS THAT WHAT YOU COMMUNICATED TO CMS?
02:38PM 23 A. YES, I BELIEVE SO.
02:38PM 24 Q. AND WAS THAT YOUR VIEW AT THE TIME?
02:38PM 25 A. YES, IT WAS.

02:38PM 1 Q. IN CORRECTIVE ACTION IT READS, "THE FRACTION OF PATIENT
02:38PM 2 RESULTS TRULY IMPACTED, AND THE NATURE AND MAGNITUDE OF ANY
02:38PM 3 EFFECT ARE UNKNOWN. OUT OF AN ABUNDANCE OF CAUTION, THE
02:38PM 4 LABORATORY HAS VOIDED ALL PATIENT TEST RESULTS REPORTED FROM
02:38PM 5 THE TPS 3.5 INSTRUMENTS."

02:38PM 6 DO YOU SEE THAT?

02:38PM 7 A. I DO SEE THAT.

02:38PM 8 Q. OKAY. AND DID YOU, IN FACT, VOID ALL OF THE TEST RESULTS
02:38PM 9 FROM THE EDISON DEVICE FROM THE 2014, 2015 TIME PERIOD?

02:39PM 10 A. YES, WE DID SO.

02:39PM 11 Q. OKAY. AND THEN IT SAYS, "MANY CORRECTED REPORTS HAVE BEEN
02:39PM 12 TRANSMITTED AND THE REMAINDER ARE BEING TRANSMITTED.

02:39PM 13 TRANSMISSION WILL BE COMPLETE BY MARCH 31ST, 2016."

02:39PM 14 DO YOU SEE THAT LANGUAGE?

02:39PM 15 A. YES, I DO.

02:39PM 16 Q. DID YOU HAVE DISCUSSIONS WITH MS. HOLMES ABOUT HOW TO
02:39PM 17 COMMUNICATE THE VOIDING OF THE TESTS TO CMS AND OTHER
02:39PM 18 CONSTITUENCIES?

02:39PM 19 A. COULD YOU BE MORE SPECIFIC.

02:39PM 20 Q. DID YOU HAVE CONVERSATIONS WITH MS. HOLMES ABOUT HOW TO
02:39PM 21 COMMUNICATE THERANOS'S VOIDING OF THE TESTS?

02:39PM 22 A. YES, WE DID.

02:39PM 23 Q. DESCRIBE THE SUBSTANCE OF WHAT WAS SAID?

02:39PM 24 A. I DESCRIBED OUR RATIONALE FOR VOIDING THESE TESTS WHICH
02:39PM 25 RELIED ON SOME OF THE THINGS THAT WE DISCUSSED EARLIER, WHICH

02:39PM 1 WAS THE VALIDATION DATA AS WELL AS THE QC DATA THAT IS
02:39PM 2 REFERENCED HERE, AS WELL AS THE PATIENT TEST RESULTS THAT WERE
02:40PM 3 REFERENCED HERE, AND IT WAS -- I CAN'T REMEMBER ALL OF THE
02:40PM 4 CONSTITUENTS AT THAT MEETING, BUT I TRIED TO PRESENT IT IN A
02:40PM 5 MORE UNDERSTANDABLE FORMAT.

02:40PM 6 SO I DESCRIBED THE ISSUE IN TERMS OF THE VALIDATION DATA
02:40PM 7 IN DESCRIBING THAT THESE INSTRUMENTS APPARENTLY WERE NOT
02:40PM 8 PERFORMING FROM THE VERY BEGINNING.

02:40PM 9 Q. AND DID MS. HOLMES MAKE ANY STATEMENTS TO YOU ABOUT
02:40PM 10 WHETHER WHAT YOU JUST SAID SHOULD BE COMMUNICATED TO CMS OR
02:40PM 11 WHETHER SOMETHING ELSE SHOULD BE COMMUNICATED?

02:40PM 12 A. YES. I RECALL HER OFFERING AN ALTERNATIVE EXPLANATION.

02:40PM 13 Q. TELL US ABOUT THAT, PLEASE.

02:40PM 14 A. I DON'T REMEMBER THE EXACT WORDS, BUT SHE POINTED TO ONE
02:40PM 15 OF HER DEPUTIES AND PROVIDED AN ALTERNATIVE EXPLANATION, WHICH
02:40PM 16 WAS ALONG THE LINES OF IT NOT BEING AN INSTRUMENT FAILURE
02:40PM 17 PER SE BUT RATHER THE, QUOTE, "A FAILURE OF THE QUALITY CONTROL
02:40PM 18 AND QUALITY ASSURANCE PROGRAM AROUND IT."

02:41PM 19 Q. AND DID YOU THINK IT WAS A COMPLETE EXPLANATION TO
02:41PM 20 DESCRIBE IT AS JUST A QUALITY CONTROL ISSUE?

02:41PM 21 A. NO, SIR.

02:41PM 22 Q. HOW COME?

02:41PM 23 A. BECAUSE THE VALIDATION DATA HAD NO BEARING ON THE QUALITY
02:41PM 24 CONTROL OR QUALITY ASSURANCE PROGRAM.

02:41PM 25 Q. AFTER THE TESTS WERE VOIDED, DR. DAS, DID THERANOS EVER

03:24PM 1 LABORATORY MUST ESTABLISH AND FOLLOW WRITTEN POLICIES AND
03:24PM 2 PROCEDURES FOR AN ONGOING MECHANISM TO MONITOR, ASSESS, AND
03:25PM 3 WHEN INDICATED, CORRECT PROBLEMS IDENTIFIED IN THE ANALYTIC
03:25PM 4 SYSTEMS SPECIFIED."

03:25PM 5 DO YOU SEE THAT LANGUAGE?

03:25PM 6 A. YES.

03:25PM 7 Q. AND IS THAT ESSENTIALLY SPELLING OUT THE CLIA REQUIREMENT?

03:25PM 8 A. YES.

03:25PM 9 Q. OKAY. AND IF WE CAN GO TO PAGE 52, MS. HOLLIMAN, I THINK
03:25PM 10 ONLY THE TOP PORTION GOING -- THERE WE GO.

03:25PM 11 IF WE COULD HIGHLIGHT THE TOP PORTION OF THIS PAGE.

03:25PM 12 DR. DAS, DO YOU SEE THE REGULATORY REQUIREMENT CONTINUES
03:25PM 13 IN COLUMN 2 BENEATH THE WORDS "CONTINUED FROM PAGE 47"?

03:25PM 14 A. YES.

03:25PM 15 Q. IS THAT HOW YOU READ THIS DOCUMENT?

03:25PM 16 A. YES.

03:25PM 17 Q. AND THEN IT SAYS, "THIS STANDARD IS NOT MET AS EVIDENCED
03:26PM 18 BY."

03:26PM 19 DO YOU SEE THAT LANGUAGE?

03:26PM 20 A. YES.

03:26PM 21 Q. AND IS STANDARD A TERM OF ART IN THE CLIA REGULATIONS?

03:26PM 22 A. YES.

03:26PM 23 Q. AND HOW DOES A STANDARD COMPARE TO A CONDITION?

03:26PM 24 A. I BELIEVE IT IS LESS SEVERE.

03:26PM 25 Q. THEN DOES THE FORMAT OF THE 2567 LAY OUT PARTICULAR

03:26PM 1 FINDINGS BY CMS AS TO HOW, IN CMS'S VIEW, THAT STANDARD WAS NOT
03:26PM 2 MET?

03:26PM 3 A. YES.

03:26PM 4 Q. AND THAT'S WHAT YOU'RE TRYING TO RESPOND TO IN THE COURSE
03:26PM 5 OF YOUR WORK?

03:26PM 6 A. YES.

03:26PM 7 Q. IF WE CAN GO TO PAGE 53, DO YOU SEE THE FINDING AT THE
03:26PM 8 BOTTOM, "BASED ON REVIEW OF QUALITY CONTROL DATA AND MONTHLY QC
03:27PM 9 REPORTS, THE LABORATORY FAILED TO HAVE A QUALITY ASSESSMENT
03:27PM 10 PROCEDURE TO IDENTIFY AND CORRECT PROBLEMS WITH QC VALUES FOR
03:27PM 11 THE THERANOS PROPRIETARY SYSTEM (TPS) WHEN PRECISION DID NOT
03:27PM 12 MEET THE LABORATORY'S REQUIREMENT FOR PRECISION."

03:27PM 13 DO YOU SEE THAT?

03:27PM 14 A. YES.

03:27PM 15 Q. AND IS PRECISION A TERM THAT YOU'RE FAMILIAR WITH IN YOUR
03:27PM 16 WORK AS THE LAB DIRECTOR?

03:27PM 17 A. YES.

03:27PM 18 Q. AND WHAT IS PRECISION?

03:27PM 19 A. IT'S A MEASURE OF THE SPREAD OF DATA.

03:27PM 20 Q. AND IN THE COURSE OF RESPONDING TO THE 2567, DID YOU
03:27PM 21 REVIEW A BROAD RANGE OF PRECISION DATA?

03:27PM 22 A. YES.

03:27PM 23 Q. LET'S GO TO PAGE 54, AND IF WE COULD ZOOM IN,
03:27PM 24 MS. HOLLIMAN, ON THE TAGS DOWN TO D.

03:28PM 25 DO YOU SEE IN B, DR. DAS, WHERE IT SAYS, "QC RESULTS WERE

03:28PM 1 REVIEWED FROM JUNE 2014 THROUGH NOVEMBER 2014 AND JANUARY
03:28PM 2 THROUGH FEBRUARY 2015 FOR VITAMIN B12, VITAMIN D, AND SEX
03:28PM 3 HORMONE BINDING GLOBULIN WHICH WERE USED FOR PATIENT TESTING ON
03:28PM 4 THE TPS DEVICES."

03:28PM 5 DO YOU SEE THAT LANGUAGE?

03:28PM 6 A. YES.

03:28PM 7 Q. AND IS THIS ALSO DATA THAT YOU REVIEWED IN THE COURSE OF
03:28PM 8 YOUR WORK?

03:28PM 9 A. YES.

03:28PM 10 Q. IN C IT SAYS, "VITAMIN B12 QC LEVEL 1 AND LEVEL 3 ON
03:28PM 11 DEVICE E 110 REVEALED THE FOLLOWING PERCENT CV: 34.3 PERCENT
03:28PM 12 AND 48.5 PERCENT RESPECTIVELY FROM JANUARY 5TH, '15 THROUGH
03:29PM 13 1-30-15."

03:29PM 14 DO YOU SEE THAT LANGUAGE?

03:29PM 15 A. YES.

03:29PM 16 Q. AND THE DEVICE E 110, DID YOU UNDERSTAND THAT TO REFER TO
03:29PM 17 A PARTICULAR EDISON DEVICE WITHIN THE LAB? DID YOU UNDERSTAND
03:29PM 18 THAT TO REFER TO A DEVICE WITHIN THE LAB?

03:29PM 19 A. YES.

03:29PM 20 Q. AND THE QC LEVEL 1 AND LEVEL 3, WHAT DID YOU UNDERSTAND
03:29PM 21 THOSE TO REFER TO?

03:29PM 22 A. THOSE ARE DIFFERENT LEVELS OF THE RESPECTIVE TEST QC, IN
03:29PM 23 THIS CASE VITAMIN B12.

03:29PM 24 Q. AND CAN YOU -- AND WHAT IS THE PURPOSE OF DIFFERENT
03:29PM 25 LEVELS?

03:29PM 1
03:29PM 2
03:29PM 3
03:29PM 4
03:29PM 5
03:29PM 6
03:29PM 7
03:30PM 8
03:30PM 9
03:30PM 10
03:30PM 11
03:30PM 12
03:30PM 13
03:30PM 14
03:30PM 15
03:30PM 16
03:30PM 17
03:30PM 18
03:30PM 19
03:30PM 20
03:30PM 21
03:30PM 22
03:30PM 23
03:30PM 24
03:30PM 25

A. A LABORATORY IS REQUIRED TO RUN MULTIPLE LEVELS FOR EVERY
QUANTITATIVE TEST, SO --

Q. SO A HIGH LEVEL, A LOW LEVEL, SOMETHING IN BETWEEN?

A. CORRECT.

Q. OKAY. AND THIS SAYS THE QC LEVEL 1 AND 3 WERE 34.3 AND
48.5 PERCENT.

WHAT WAS -- WHAT DID YOU UNDERSTAND THAT TO MEAN?

A. IT APPEARS THEY'RE REFERENCING THOSE PARTICULAR LEVELS FOR
THOSE QC.

Q. AND ARE THESE DESIRABLE LEVELS OF QC OR UNDESIRABLE LEVELS
OF QC?

A. THOSE WOULD BE UNDESIRABLE.

Q. AND IS THIS SOMETHING THAT YOU LOOKED INTO AS THE
LABORATORY DIRECTOR?

A. YES.

Q. AND IF WE COULD ZOOM IN.

IN D THERE'S SOME REFERENCE TO VITAMIN B12, QC1, AND QC3
ON DEVICE E 1085.

IS THIS SIMILAR INFORMATION RELATING TO A DIFFERENT EDISON
DEVICE THAT WAS BEING USED IN THE CLIA LAB?

A. YES.

Q. AND IS THAT SOMETHING THAT YOU INVESTIGATED?

A. YES.

Q. IF WE CAN ZOOM OUT, MS. HOLLIMAN, AND LOOK AT E THROUGH L,
OR E THROUGH LITTLE I.

03:41PM 1 FROM APRIL 1ST, 2015 THROUGH 9/16/15."

03:41PM 2 DO YOU SEE THAT LANGUAGE?

03:41PM 3 A. YES.

03:41PM 4 Q. AND WHAT WAS THE THRUST OF THE DEFICIENCY AS YOU
03:41PM 5 UNDERSTOOD IT THAT WAS BEING BROUGHT TO YOUR ATTENTION?

03:41PM 6 A. WHAT IS BEING REFERENCED HERE IS THAT PATIENT RESULTS WERE
03:41PM 7 RECORDED WHEN QUALITY CONTROLS WERE NOT RECORDED.

03:41PM 8 Q. AND EXPLAIN WHY THAT'S, EXPLAIN WHY THAT'S AN ISSUE.

03:41PM 9 A. QUALITY CONTROL MUST BE RUN DAILY WHEN PATIENT TEST
03:41PM 10 RESULTS ARE BEING RUN ON ANY ASSAY.

03:41PM 11 Q. SO IF YOU RUN QUALITY CONTROL AND YOU FAIL QUALITY CONTROL
03:41PM 12 FOR WHATEVER REASON, YOU SHOULDN'T BE REPORTING A TEST?

03:41PM 13 A. THAT'S RIGHT.

03:41PM 14 Q. AND IS THIS LISTING EXAMPLES OF WHERE IT APPEARED THAT
03:41PM 15 THERANOS WAS RUNNING TESTS AFTER NOT PASSING QUALITY CONTROL?

03:41PM 16 A. YES.

03:41PM 17 MR. WADE: YOUR HONOR, MOVE TO STRIKE. IT'S BEYOND
03:42PM 18 THE SCOPE OF WHAT THE EVIDENCE IS OFFERED FOR.

03:42PM 19 THE COURT: YOU CAN ASK THAT IN A DIFFERENT WAY.

03:42PM 20 I'LL SUSTAIN THE OBJECTION AND STRIKE THAT ANSWER.

03:42PM 21 BY MR. LEACH:

03:42PM 22 Q. AS PART OF YOUR WORK, DR. DAS, DID YOU INVESTIGATE WHETHER
03:42PM 23 THERE WERE INSTANCES WHERE THERANOS REPORTED PATIENT RESULTS
03:42PM 24 AFTER NOT PASSING QUALITY CONTROL?

03:42PM 25 A. YES.

03:42PM 1

Q. AND DID YOU FIND EXAMPLES OF THAT RELATING TO PT INR?

03:42PM 2

A. YES.

03:42PM 3

MR. WADE: 702, YOUR HONOR.

03:42PM 4

THE COURT: OVERRULED.

03:42PM 5

BY MR. LEACH:

03:42PM 6

Q. YOU FOUND EXAMPLES OF THAT?

03:42PM 7

A. YES.

03:42PM 8

Q. DID YOU ALSO -- LOOKING DOWN AT PARAGRAPH 2, DO YOU SEE

03:42PM 9

THAT THE FINDING HERE IS BASED ON A REVIEW OF THE QUALITY

03:42PM 10

CONTROL PROCEDURE, QC RECORDS, AND RAW DATA FROM PATIENT TEST

03:43PM 11

RUNS AND INTERVIEW WITH THE GENERAL SUPERVISOR, THE LABORATORY

03:43PM 12

FAILED TO ENSURE THAT THE QC WAS ACCEPTABLE FOR THE TPS SYSTEM,

03:43PM 13

OR THERANOS PROPRIETARY SYSTEM, PRIOR TO REPORTING PATIENT TEST

03:43PM 14

RESULTS.

03:43PM 15

DO YOU SEE THAT?

03:43PM 16

A. YES.

03:43PM 17

Q. IN YOUR MIND, WAS THIS RAISING A SIMILAR ISSUE WITH THE

03:43PM 18

EDISONS THAT WAS RAISED WITH RESPECT TO PT INR?

03:43PM 19

A. YES.

03:43PM 20

MR. WADE: 702, YOUR HONOR.

03:43PM 21

THE COURT: OVERRULED.

03:43PM 22

BY MR. LEACH:

03:43PM 23

Q. AND DID YOU INVESTIGATE WHETHER THERE WERE INSTANCES WHERE

03:43PM 24

THERANOS REPORTED PATIENT RESULTS FROM THE EDISON DEVICE AFTER

03:43PM 25

FAILING QUALITY CONTROL?

03:45PM 1 Q. AND YOU FOUND INSTANCES WHERE THAT HAPPENED?

03:45PM 2 A. YES.

03:45PM 3 Q. LET ME DRAW YOUR ATTENTION, PLEASE, TO PAGE 43. AND I

03:45PM 4 WANT TO DRAW YOUR ATTENTION TO THE FINDING L AT THE BOTTOM.

03:45PM 5 DO YOU SEE WHERE IT SAYS, "QC RECORDS FOR VITAMIN B12

03:45PM 6 SHOWED THAT ON DEVICE E 37, QC1 HAD A '10X WARNING' MESSAGE"?

03:46PM 7 A. YES.

03:46PM 8 Q. AND WHAT IS A 10X WARNING MESSAGE?

03:46PM 9 A. THAT IS REFERRING TO A QUALITY CONTROL FAILURE WHERE THE

03:46PM 10 QUALITY CONTROL RESULTS LIE ON ONE SIDE OF THE MEAN EITHER

03:46PM 11 ABOVE OR BELOW TEN TIMES CONSECUTIVELY.

03:46PM 12 Q. AND IN THE COURSE OF YOUR WORK, DID YOU SEE INSTANCES

03:46PM 13 WHERE THERANOS CONTINUED TO REPORT PATIENT RESULTS AFTER THIS

03:46PM 14 10X WARNING HAD COME UP?

03:46PM 15 A. YES.

03:46PM 16 Q. PLEASE LOOK AT THE NEXT PAGE, PAGE 44.

03:46PM 17 AND IF I COULD FOCUS ON THE SECOND HALF BEGINNING WITH THE
03:46PM 18 FINDING AT O THROUGH Q.

03:46PM 19 DO YOU SEE, DR. DAS, WHERE IT SAYS, "LEVEY-JENNINGS CHARTS
03:47PM 20 REVEALED THAT SHBG DEVICE E 26 QC1 HAD 13 CONSECUTIVE DAYS AND
03:47PM 21 QC2 HAD 15 CONSECUTIVE DAYS THAT THE RESULTS WERE AT LEAST TWO
03:47PM 22 STANDARD DEVIATIONS BELOW THE MEAN FROM SEPTEMBER 30TH, 2014,
03:47PM 23 THROUGH 10/29/14."

03:47PM 24 DO YOU SEE THAT LANGUAGE?

03:47PM 25 A. YES.

03:47PM 1
03:47PM 2
03:47PM 3
03:47PM 4
03:47PM 5
03:47PM 6
03:47PM 7
03:47PM 8
03:47PM 9
03:47PM 10
03:47PM 11
03:47PM 12
03:48PM 13
03:48PM 14
03:48PM 15
03:48PM 16
03:48PM 17
03:48PM 18
03:48PM 19
03:48PM 20
03:48PM 21
03:48PM 22
03:48PM 23
03:48PM 24
03:49PM 25

Q. DID YOU ALSO REVIEW LEVEY-JENNINGS CHARTS IN THE COURSE OF YOUR WORK IN INVESTIGATING THE 2567?

A. YES.

Q. AND IT'S BEEN A WHILE SINCE WE'VE HEARD THAT TERM, BUT WHAT IS A LEVEY-JENNINGS CHART?

A. IT'S ALSO KNOWN AS A CONTROL CHART. IT'S JUST A WAY TO CHART QUALITY CONTROL VALUES OVER TIME WITH RESPECT TO THE EXPECTED MEAN AND STANDARD DEVIATIONS.

Q. AND AT ANY POINT IN TIME DID YOU COMMUNICATE TO CMS THAT YOU DISAGREED WITH THIS FINDING?

A. NO.

Q. THAT WOULD BE TRUE OF THE FINDINGS IN P AND Q RELATED TO THE LEVY-JENNINGS CHARTS?

A. YES.

Q. WE TALKED A LITTLE BIT ABOUT --

THANK YOU, MS. HOLLIMAN. WE CAN TAKE THAT DOWN.

DURING THE COURSE OF YOUR WORK, DID YOU BECOME FAMILIAR WITH THE ARIZONA LAB, THE MODERATE COMPLEXITY ARIZONA LAB?

A. YES.

Q. AND AS A RESULT OF YOUR WORK, THE TESTING THAT WAS DONE IN THE ARIZONA LAB WAS NOT DONE ON ANY THERANOS DEVICES; IS THAT CORRECT?

A. YES.

Q. AND IT WAS NOT DONE ON ANY MODIFIED THIRD PARTY DEVICES?

A. YES.

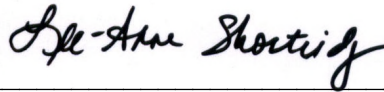
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 9, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 31
)
ELIZABETH A. HOLMES,) NOVEMBER 10, 2021
)
DEFENDANT.) PAGES 5873 - 6145
_____)

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
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JEFFREY B. SCHENK
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BY: ROBERT S. LEACH
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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
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ALSO PRESENT:

FEDERAL BUREAU OF INVESTIGATION
BY: ADELAIDA HERNANDEZ

OFFICE OF THE U.S. ATTORNEY
BY: LAKISHA HOLLIMAN, PARALEGAL
MADDI WACHS, PARALEGAL

WILLIAMS & CONNOLLY
BY: TIMIKA ADAMS-SHERMAN, PARALEGAL

TBC
BY: BRIAN BENNETT, TECHNICIAN

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GOVERNMENT'S:

KINGSHUK DAS

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REDIRECT EXAM BY MR. LEACH P. 6017

RE-CROSS-EXAM BY MR. WADE P. 6030

ALAN EISENMAN

DIRECT EXAM BY MR. BOSTIC P. 6037

CROSS-EXAM BY MR. DOWNEY P. 6101

09:56AM 1 Q. AND THEY'RE RESPONSIBLE FOR LOOKING AT THE DATA AND MAKING
09:56AM 2 SURE THAT THE POLICY IS ADHERED TO; IS THAT RIGHT?

09:56AM 3 A. YES.

09:56AM 4 Q. OKAY. AND WHEN YOU LOOKED AT THAT DATA, YOU, YOU
09:57AM 5 ULTIMATELY HAD, YOU ULTIMATELY CAME TO THE VIEW THAT SOME
09:57AM 6 REMEDIATION WAS NECESSARY; IS THAT RIGHT?

09:57AM 7 A. YES.

09:57AM 8 Q. AND I WANT TO TALK A LITTLE BIT ABOUT -- I THINK WITH
09:57AM 9 MR. LEACH YOU WERE ASKED SOME QUESTIONS ABOUT SOME OF THE
09:57AM 10 INFORMATION THAT YOU LOOKED AT.
09:57AM 11 DO YOU RECALL THAT?

09:57AM 12 A. YES.

09:57AM 13 Q. AND YOU, YOU -- WE WERE TALKING ABOUT BUCKETS, I THINK.
09:57AM 14 DO YOU RECALL THAT?

09:57AM 15 A. YES.

09:57AM 16 Q. AND THERE WERE, THERE WERE THREE BUCKETS IN PARTICULAR.
09:57AM 17 DO YOU RECALL?

09:57AM 18 A. YES.

09:57AM 19 Q. AND ONE RELATED TO THE VALIDATION OF THOSE EDISON ASSAYS;
09:57AM 20 RIGHT?

09:57AM 21 A. YES.

09:58AM 22 Q. AND THE SECOND BUCKET RELATED TO QUALITY CONTROL RESULTS;
09:58AM 23 CORRECT?

09:58AM 24 A. YES.

09:58AM 25 Q. AND THEN THE THIRD BUCKET RELATED TO WHAT I THINK YOU

09:58AM 1 DESCRIBED AS SORT OF A PATIENT TEST RESULT DISTRIBUTION

09:58AM 2 ANALYSIS; RIGHT?

09:58AM 3 A. YES.

09:58AM 4 Q. AND I JUST WANT TO MAKE SURE THAT WE ALL UNDERSTAND KIND

09:58AM 5 OF A LITTLE BIT MORE ABOUT WHAT YOU DID AND WHAT YOU CONSIDERED

09:58AM 6 THERE. OKAY?

09:58AM 7 A. YES.

09:58AM 8 Q. WITHIN 4621, THERE WAS SOME SPECIFIC DATA AND ITEMS THAT

09:58AM 9 WERE IDENTIFIED RELATING TO QUALITY CONTROL; RIGHT?

09:58AM 10 A. YES.

09:58AM 11 Q. BUT YOU -- IN PERFORMING YOUR FUNCTION, YOU DIDN'T LIMIT

09:58AM 12 YOURSELF TO JUST LOOKING AT THAT QUALITY CONTROL INFORMATION;

09:58AM 13 RIGHT?

09:58AM 14 A. YES.

09:58AM 15 Q. YOU ACTUALLY ASKED FOR ALL OF THE QUALITY CONTROL

09:58AM 16 INFORMATION WITH RESPECT TO EDISON ASSAYS TO BE EXTRACTED AND

09:59AM 17 REVIEWED; RIGHT?

09:59AM 18 A. YES.

09:59AM 19 Q. AND YOU STARTED TO TURN OVER ROCKS, IF YOU WILL?

09:59AM 20 A. YES.

09:59AM 21 Q. AND YOU DID A RETROSPECTIVE ANALYSIS OF THE QUALITY

09:59AM 22 CONTROL DATA APPLYING CERTAIN WESTGARD RULES AND PRINCIPLES TO

09:59AM 23 ASSESS THE HISTORICAL QUALITY CONTROL PERFORMANCE OF THOSE

09:59AM 24 EDISON ASSAYS; RIGHT?

09:59AM 25 A. YES.

10:03AM 1 DO YOU RECALL THAT?

10:03AM 2 A. YES.

10:03AM 3 Q. AND I'M GOING TO GO INTO THOSE IN A SECOND. BEFORE I DO,
10:03AM 4 I JUST WANT TO GO INTO THE THIRD BUCKET, WHICH WAS THE PATIENT
10:04AM 5 TEST DISTRIBUTION RESULTS. OKAY?

10:04AM 6 A. YES.

10:04AM 7 Q. AND THERE WHAT YOU DID IS FOR EACH OF THE ASSAYS YOU
10:04AM 8 ESSENTIALLY PULLED OUT OF THE LIS ALL OF THE PATIENT RESULTS
10:04AM 9 FOR EACH ASSAY; RIGHT?

10:04AM 10 A. I'M NOT SURE WHERE THE DATA WAS PULLED FROM. IT WAS
10:04AM 11 PULLED FOR OUR TEAM.

10:04AM 12 Q. OKAY. WHEREVER THE DATA WAS -- FOR PATIENT RESULTS WAS
10:04AM 13 MAINTAINED, ALL OF THAT DATA WAS EXTRACTED; CORRECT?

10:04AM 14 A. YES, THAT WAS TRUE TO THE BEST OF MY UNDERSTANDING.

10:04AM 15 Q. OKAY. AND YOU LOOKED AT ALL OF THE RESULTS AND LOOKED AT
10:04AM 16 SORT OF WHETHER THEY -- HOW THEY PERFORMED WITHIN THE REFERENCE
10:04AM 17 RANGE.

10:04AM 18 IS THAT --

10:04AM 19 A. TO SOME EXTENT.

10:04AM 20 Q. CAN YOU GIVE US A SENSE OF WHAT THE PATIENT DISTRIBUTION
10:04AM 21 ANALYSIS CONSISTS OF?

10:04AM 22 A. I'LL TRY TO AVOID JARGON AS MUCH AS POSSIBLE.

10:04AM 23 IN GENERAL, WE WERE TRYING TO ASSESS HOW THE AVERAGE
10:05AM 24 VALUES WERE CHANGING OR NOT CHANGING OVER TIME, WHICH IS A
10:05AM 25 REFLECTION OF INACCURACY WITH THE TEST.

10:05AM 1 ALSO, YOU CAN LOOK AT WHAT YOU WERE DESCRIBING, THE
10:05AM 2 DISTRIBUTIONS OF ABNORMALS VERSUS NORMALS, AND GET A SENSE OF
10:05AM 3 ANY SORT OF IMPRECISION IN THE ASSAY.
10:05AM 4 THERE'S VARIOUS WAYS TO LOOK AT THESE METRICS. BUT, YES
10:05AM 5 IN GENERAL.
10:05AM 6 Q. SO YOU ESSENTIALLY PLOT ALL OF THE RESULTS FOR THE
10:05AM 7 PATIENTS AND SORT OF LOOK AT AND ANALYZE THE DATA AND CONSIDER
10:05AM 8 WHETHER YOU CAN INFER ANYTHING FROM ALL OF THE RESULTS FOR THAT
10:05AM 9 PARTICULAR ASSAY?
10:05AM 10 A. TO SOME EXTENT, YES. WE MAKE CALCULATIONS BASED ON THE
10:05AM 11 ENTIRE DATA SET AND LOOK AT IT IN CHUNKS. BUT, BUT OVERALL,
10:05AM 12 YES.
10:05AM 13 Q. OKAY. AND THESE, THESE THREE BUCKETS THAT YOU'RE TALKING
10:05AM 14 ABOUT, THIS IS A PRETTY SOPHISTICATED ANALYSIS; IS THAT FAIR?
10:05AM 15 A. YES.
10:05AM 16 Q. AND IT REQUIRED THE EXTRACTION OF A LOT OF DATA; RIGHT?
10:06AM 17 A. YES.
10:06AM 18 Q. AND IT REQUIRED THE CONSIDERATION AND ANALYSIS OF A LOT OF
10:06AM 19 THAT DATA IN ORDER TO INFORM YOUR VIEWS; RIGHT?
10:06AM 20 A. YES.
10:06AM 21 Q. THIS IS NOT SOMETHING THAT IN YOUR VIEW SOMEONE WITHOUT
10:06AM 22 KNOWLEDGE AND TRAINING WOULD BE IN A POSITION TO DO; IS THAT
10:06AM 23 FAIR?
10:06AM 24 A. CORRECT.
10:06AM 25 Q. OKAY. AND AS A RESULT OF THAT COMBINATION OF INFORMATION,

10:27AM 1 A. YES, I WAS USING THAT AS AN EXAMPLE.

10:27AM 2 Q. AND MANY OF THE ANALYSES THAT YOU WERE DOING WERE PRETTY
10:28AM 3 TECHNICAL IN NATURE; RIGHT?

10:28AM 4 A. YES.

10:28AM 5 Q. AND MS. HOLMES'S DIDN'T HAVE THAT SORT OF TECHNICAL
10:28AM 6 BACKGROUND; RIGHT?

10:28AM 7 A. YES.

10:28AM 8 Q. AND SO YOU WERE TRYING -- AND SHE HAD NOT SUPERVISED THE
10:28AM 9 LAB PREVIOUSLY TO YOUR KNOWLEDGE; RIGHT?

10:28AM 10 A. CORRECT.

10:28AM 11 Q. AND SO YOU WERE TRYING TO KIND OF BRIEF HER IN ON SOME OF
10:28AM 12 THESE CONCEPTS AND EXPLAIN TO HER WHY YOU CAME TO THE VIEWS
10:28AM 13 THAT YOU CAME TO; IS THAT FAIR?

10:28AM 14 A. YES.

10:28AM 15 Q. AND SO WHILE DOING THAT, IS IT FAIR TO SAY THAT IN SOME
10:28AM 16 WAY YOU WERE DESCRIBING, OR TRYING TO DESCRIBE, THESE THREE
10:28AM 17 BUCKETS AND HOW YOUR VIEWS WERE INFORMED?

10:28AM 18 A. YES.

10:28AM 19 Q. AND YOU USED, AS AN EXAMPLE OF THAT, THE PSA ASSAY TO NOTE
10:28AM 20 THAT PSA WAS DETECTED IN SOME FEMALE PATIENTS, WHICH WAS
10:28AM 21 UNUSUAL; RIGHT?

10:28AM 22 A. YES.

10:28AM 23 Q. AND DID YOU COME TO UNDERSTAND THAT MS. HOLMES HAD
10:29AM 24 PROVIDED SOME KIND OF A STUDY BY ANOTHER ADVISOR THAT SUGGESTED
10:29AM 25 THAT PSA COULD SOMETIMES BE DETECTED IN FEMALES?

12:44PM 1 HE SAID HE DOESN'T KNOW WHAT HAPPENED AND --

12:45PM 2 THE COURT: WELL, I'LL ALLOW IT. I THINK YOU'RE
12:45PM 3 ABOUT DONE WITH THIS.

12:45PM 4 MR. LEACH: I'M ABOUT DONE, YOUR HONOR. THANK YOU.

12:45PM 5 Q. YOU WERE ALSO ASKED SOME QUESTIONS ABOUT SOME OF THE
12:45PM 6 QUALITY CONTROL DATA THAT WAS REPORTED IN THE CMS REPORT.

12:45PM 7 DO YOU RECALL SOME QUESTIONS ABOUT THAT?

12:45PM 8 A. YES.

12:45PM 9 Q. AND IN RESPONSE TO THE 2567, YOU REVIEWED NOT JUST THE
12:45PM 10 QUALITY CONTROL DATA THAT WAS LISTED IN THE CMS REPORT, BUT A
12:45PM 11 BROADER UNIVERSE OF DATA.

12:45PM 12 IS THAT FAIR?

12:45PM 13 A. YES.

12:45PM 14 Q. AND WHAT WAS THE REASON FOR DOING THAT?

12:45PM 15 A. THAT WAS TO IDENTIFY THE EXTENT OF THE DEFICIENCY.

12:45PM 16 Q. OKAY. AND AFTER THAT BROADER REVIEW, DID YOU VIEW THE
12:45PM 17 INSTANCES THAT WERE LISTED BY CMS AS REPRESENTATIVE SAMPLES?

12:45PM 18 A. YES.

12:45PM 19 Q. THOSE DIDN'T SEEM OUT OF -- UNUSUAL IN THE SENSE OF BEING
12:45PM 20 ONE OFFS OR OUT OF THE ORDINARY?

12:45PM 21 A. OUTLIERS? IS THAT CORRECT?

12:46PM 22 Q. WE'VE USED THAT TERM IN SOME OTHER CONTEXTS. I JUST WANT
12:46PM 23 TO MAKE SURE IF WHAT WAS REPORTED IN CMS WAS REPRESENTATIVE OF
12:46PM 24 WHAT YOU SAW IN YOUR BROADER REVIEW.

12:46PM 25 A. YES.

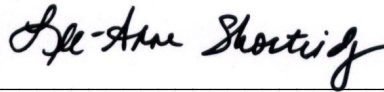
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 10, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) VOLUME 33
)
ELIZABETH A. HOLMES,) NOVEMBER 16, 2021
)
DEFENDANT.) PAGES 6302 - 6573
) **SEALED PAGES 6566 - 6573**

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
LANCE A. WADE
KATHERINE TREFZ
PATRICK LOOBY
SEEMA ROPER
RICHARD CLEARY
J.R. FLEURMONT
725 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20005

LAW OFFICE OF JOHN D. CLINE
BY: JOHN D. CLINE
ONE EMBARCADERO CENTER, SUITE 500
SAN FRANCISCO, CALIFORNIA 94111

ALSO PRESENT: FEDERAL BUREAU OF INVESTIGATION
BY: ADELAIDA HERNANDEZ

OFFICE OF THE U.S. ATTORNEY
BY: LAKISHA HOLLIMAN, PARALEGAL
MADDI WACHS, PARALEGAL

WILLIAMS & CONNOLLY
BY: TIMIKA ADAMS-SHERMAN, PARALEGAL

TBC
BY: BRIAN BENNETT, TECHNICIAN

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CROSS-EXAM BY MR. WADE

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BRIAN GROSSMAN

DIRECT EXAM BY MR. LEACH

P. 6374

CROSS-EXAM BY MR. WADE

P. 6462

09:21AM 1 OF PAGES OF CUSTOMER REPORTS THAT WERE GENERALLY NEGATIVE ABOUT
09:21AM 2 THERANOS, RELATING TO THINGS LIKE DISTANCE BETWEEN A CUSTOMER'S
09:21AM 3 HOME AND A STORE, THE AMOUNT OF TIME THAT THEY HAD TO WAIT IN
09:21AM 4 LINE, HOW CLEAN THE FACILITIES WERE, HOW FRIENDLY PEOPLE WERE,
09:21AM 5 A LOT OF NEGATIVE INFORMATION ON THOSE ANCILLARY UNRELATED
09:21AM 6 POINTS.

09:21AM 7 THE DEFENSE WOULD BE MAKING THE SAME ARGUMENTS THAT I AM
09:21AM 8 MAKING HERE TODAY, AND THEY WOULD BE RIGHT TO DO SO.

09:21AM 9 CUSTOMER FEEDBACK ON THESE ISSUES IS NOT RELEVANT TO THE
09:21AM 10 CASE, REGARDLESS OF WHETHER IT'S FAVORABLE OR NOT. THE FACT
09:21AM 11 THAT IT'S FAVORABLE RAISES 403 CONCERNS WITH THE GOVERNMENT,
09:21AM 12 AND IT'S INADMISSIBLE FOR THE REASONS THAT I'VE DESCRIBED.

09:21AM 13 THE COURT: THANK YOU.

09:21AM 14 MR. CLEARY, THE LAST WORD.

09:21AM 15 MR. CLEARY: THIS IS POWERFUL EVIDENCE OF
09:21AM 16 MS. HOLMES'S STATE OF MIND. WE BELIEVE THAT IT SHOULD BE
09:21AM 17 ADMITTED, AND WE BELIEVE THAT EXCLUDING IT FOR THE REASONS THAT
09:21AM 18 THE GOVERNMENT INVITES THE COURT TO DO SO WOULD SERIOUSLY
09:22AM 19 MISLEAD THE JURY AS TO THE INFORMATION SENT AND SHARED TO
09:22AM 20 MS. HOLMES ABOUT CRITICAL ALLEGATIONS IN THE CASE AND WOULD
09:22AM 21 UNFAIRLY PREJUDICE OUR DEFENSE.

09:22AM 22 THE COURT: THANK YOU VERY MUCH. THANK YOU.

09:22AM 23 AND THANK YOU FOR YOUR PLEADINGS AND THE ARGUMENT THIS
09:22AM 24 MORNING.

09:22AM 25 MR. CLEARY, I DON'T SEE ANYTHING THAT CAUSES ME TO DISTURB

09:22AM 1 THE COURT'S PREVIOUS RULING IN THIS MATTER. I UNDERSTAND YOUR
09:22AM 2 VIEW AND YOUR TEAM'S VIEW THAT THIS IS CRITICALLY IMPORTANT TO
09:22AM 3 SHOW YOUR CLIENT'S STATE OF MIND AS TO THE NEGOTIATION THAT SHE
09:22AM 4 HAD, AND THIS WOULD BETTER INFORM HER OF THE INFORMATION RATHER
09:22AM 5 THAN THE INFORMATION THAT SHE RECEIVED FROM WALGREENS, ET
09:22AM 6 CETERA. I KNOW YOU COMMENTED ON THAT'S A FACT ISSUE AND THAT'S
09:22AM 7 AN ISSUE THAT THE JURY COULD WRESTLE WITH IF THIS INFORMATION
09:22AM 8 IS ADMITTED.

09:22AM 9 BUT AS A THRESHOLD ISSUE, I JUST DON'T SEE THAT IT'S
09:22AM 10 RELEVANT TO THE ISSUES IN THE INDICTMENT, NOTWITHSTANDING THE
09:22AM 11 FACT THAT PRICE IS MENTIONED. THIS IS NOT A PRICING CASE,
09:22AM 12 QUOTE-UNQUOTE.

09:22AM 13 IT'S NOT A -- THE ALLEGATIONS ARE NOT SPECIFIC THAT ONE
09:23AM 14 PRICE WAS PROMISED AND A DIFFERENT PRICE WAS OBTAINED. IT'S
09:23AM 15 NOT BAIT AND SWITCH.

09:23AM 16 PRICE IS PERHAPS AN ANCILLARY PART OF THE CASE, AND I
09:23AM 17 APPRECIATE THAT.

09:23AM 18 BUT THE REAL ISSUES IN THE CASE I THINK ARE CONTAINED IN
09:23AM 19 12(D), WHICH TALK ABOUT THE ACCURACY OF THE TEST RESULTS.
09:23AM 20 THAT'S REALLY WHAT THE FOCUS OF THE PROSECUTION IS.

09:23AM 21 I DON'T HEAR THE GOVERNMENT SAYING THAT THEY'RE GOING TO
09:23AM 22 ARGUE THAT PRICING IN ANY WAY, THE FALSITY OF PRICING WAS AN
09:23AM 23 ISSUE.

09:23AM 24 I JUST DON'T SEE ANYTHING THAT CAUSES ME TO DISTURB THE
09:23AM 25 COURT'S PREVIOUS RULING ON THIS MATTER, AND I'M GOING TO

09:23AM 1 RESPECTFULLY DECLINE YOUR INVITATION TO CHANGE THAT POSITION.

09:23AM 2 I AM INFORMED WHEN I LOOK AT THE TIMING AND THE RANGES OF

09:23AM 3 THIS INFORMATION, I THINK THAT'S IMPORTANT ALSO. THAT WAS

09:23AM 4 POINTED OUT DURING OUR DISCUSSION. I JUST DON'T SEE THE

09:23AM 5 RELEVANCE OF THIS.

09:23AM 6 AND EVEN UNDER A 403 ANALYSIS, I DO THINK THAT THIS

09:24AM 7 INFORMATION, THE PROBATIVE VALUE IS OUTWEIGHED BY ANY

09:24AM 8 PREJUDICIAL VALUE, AS WELL AS ANY TIME CONSUMPTION THAT IS

09:24AM 9 GOING TO BE REQUIRED TO LOOK THROUGH THESE DOCUMENTS FOR THAT

09:24AM 10 PROBATIVE, MINIMAL, MINIMAL PROBATIVE VALUE.

09:24AM 11 SO I'M GOING TO RESPECTFULLY DECLINE YOUR INVITATION TO

09:24AM 12 DISTURB THE COURT'S PREVIOUS RULING ON THESE MATTERS. THESE

09:24AM 13 WILL CONTINUE TO BE EXCLUDED.

09:24AM 14 SO THANK YOU VERY MUCH.

09:24AM 15 THANK YOU, MR. CLEARY.

09:24AM 16 THANK YOU, MR. BOSTIC.

09:24AM 17 MR. BOSTIC: THANK YOU, YOUR HONOR.

09:24AM 18 THE COURT: I APPRECIATE IT.

09:24AM 19 ANYTHING ELSE BEFORE WE BRING IN THE JURY?

09:24AM 20 MR. BOSTIC: YOUR HONOR, I'M NOT SURE WHETHER THE

09:24AM 21 COURT WANTED TO DO THIS IN THE JURY'S PRESENCE OR NOT, BUT I

09:24AM 22 UNDERSTAND FROM THE DEFENSE THAT THEY HAD NO OBJECTION TO

09:24AM 23 EXCUSING MR. EISENMAN.

09:24AM 24 WE SO INFORMED HIM, AND I BELIEVE HE HAS TRAVELLED OUT OF

09:24AM 25 TOWN. WE JUST WANTED TO PUT THAT ON THE RECORD.

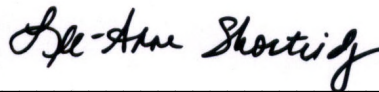
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
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CERTIFICATE NUMBER 8076



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CERTIFICATE NUMBER 9595

DATED: NOVEMBER 16, 2021

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CR-18-00258-EJD
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)
VS.) VOLUME 34
)
ELIZABETH A. HOLMES,) NOVEMBER 17, 2021
)
DEFENDANT.) PAGES 6574 - 6779
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INDEX OF PROCEEDINGS

GOVERNMENT'S:

BRIAN GROSSMAN

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E. T.

DIRECT EXAM BY MR. BOSTIC

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CROSS-EXAM BY MS. TREFZ

P. 6762

03:19PM 1 DO YOU SEE THAT?

03:19PM 2 A. I DO, YES.

03:19PM 3 Q. DO YOU REMEMBER RECEIVING THESE RESULTS IN MAY 2015?

03:19PM 4 A. I DO.

03:19PM 5 Q. LET'S LOOK AT THE NEXT PAGE, WHICH IS PAGE 2 OF
03:19PM 6 EXHIBIT 5483. AND LET'S ZOOM IN ON THE BOX IN THE MIDDLE OF
03:20PM 7 THE PAGE LABELLED HIV 1, 2 ANTIBODY SCREEN.

03:20PM 8 MS. T [REDACTED], DO YOU SEE A BREAKDOWN OF SOME ADDITIONAL
03:20PM 9 HIV RELATED RESULTS FROM YOUR THERANOS TEST?

03:20PM 10 A. YES.

03:20PM 11 Q. AND YOU'LL SEE AGAIN THAT THE HIV 1 PLUS 2 ANTIBODY TEST
03:20PM 12 IS MARKED AS REACTIVE.

03:20PM 13 DO YOU SEE THAT?

03:20PM 14 A. YES.

03:20PM 15 Q. AND THAT THE OTHERS FOR HIV 1 ANTIBODY, HIV 2 ANTIBODY,
03:20PM 16 AND HIV 1 RNA ARE MARKED AS NON-REACTIVE OR NOT DETECTED.

03:20PM 17 DO YOU SEE THAT?

03:20PM 18 A. YES.

03:20PM 19 Q. PRIOR TO 2015, WERE YOU EVER AT ANY TIME DIAGNOSED WITH
03:20PM 20 HIV OR AIDS?

03:20PM 21 A. NO.

03:20PM 22 Q. AT ANY TIME SINCE 2015 HAVE YOU BEEN DIAGNOSED WITH HIV OR
03:20PM 23 AIDS?

03:21PM 24 A. NO.

03:21PM 25 Q. TO YOUR KNOWLEDGE, HAVE YOU EVER HAD ANY SYMPTOMS OF HIV

03:21PM 1

OR AIDS?

03:21PM 2

A. NO.

03:21PM 3

Q. HAVE YOU EVER RECEIVED TREATMENT FOR HIV OR AIDS?

03:21PM 4

A. NO.

03:21PM 5

Q. I'D LIKE TO DRAW YOUR ATTENTION TO SOME LANGUAGE ON PAGE 3 OF THE EXHIBIT.

03:21PM 6

03:21PM 7

A. PAGE 3?

03:21PM 8

Q. PAGE 3 OF THE EXHIBIT, AT THE BOTTOM OF THE PAGE THERE'S A SECTION MARKED LAB NOTES.

03:21PM 9

03:21PM 10

DO YOU SEE THAT?

03:21PM 11

A. YES.

03:21PM 12

Q. AND IT READS THERE, "HIV ANTIBODIES WERE NOT CONFIRMED AND HIV-1 RNA WAS NOT DETECTED. NO LABORATORY EVIDENCE OF HIV-1 INFECTION. FOLLOW-UP TESTING FOR HIV-2 SHOULD BE PERFORMED IF CLINICALLY INDICATED."

03:21PM 13

03:21PM 14

03:21PM 15

03:21PM 16

DO YOU SEE THAT?

03:21PM 17

A. YES.

03:21PM 18

Q. BASED ON YOUR MEDICAL HISTORY, ARE YOU AWARE OF ANY REASON WHY HIV ANTIBODIES WOULD BE PRESENT IN YOUR BLOOD?

03:21PM 19

03:22PM 20

A. NO.

03:22PM 21

Q. FOLLOWING YOUR RECEIPT OF THESE RESULTS, DID YOU TAKE ANY STEPS TO CONFIRM THESE RESULTS OR GET A SECOND OPINION?

03:22PM 22

A. FOLLOWING MY -- I'M SORRY, CAN YOU SAY THAT AGAIN, PLEASE.

03:22PM 23

03:22PM 24

Q. AFTER YOU GOT THESE RESULTS, DID YOU TAKE ANY STEPS TO TRY TO VERIFY WHAT WAS REALLY HAPPENING?

03:22PM 25

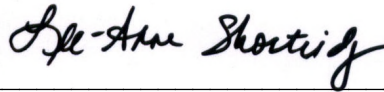
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LEE-ANNE SHORTRIDGE, CSR, CRR
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DATED: NOVEMBER 17, 2021

EXHIBIT 2

**PATENT PORTFOLIO SUMMARY**

US Patents and Applications:	315
Intl Patents and Applications:	865
Patent Portfolio Total:	1180

PATENT PORTFOLIO DETAILS

	<u>Issued</u>	<u>Pending</u>	<u>Allowed</u>	<u>Published</u>
US	103	77	11	124
Europe	94	8	2	46
China	11	5	1	48
Japan	16	7	1	41
India	2	24		21
Mexico	20	45		
WIPO/PCT		1		19
Other Intl	103	262	15	73
Total:	349	429	30	372

July 25, 2017

Proprietary and Confidential

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Allowed	13161756.5	10/10/2007	European Patent Office	Utility: Foreign Divisional	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Allowed	2666338	10/10/2007	Canada	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Allowed	2012121204	10/18/2010	Russian Federation	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Allowed	2013137661	1/20/2012	Russian Federation	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Allowed	2013/05478	1/20/2012	South Africa	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	2012318963	9/25/2012	Australia	Utility: Foreign	
SYSTEMS AND METHODS FOR COLLECTING AND TRANSMITTING ASSAY RESULTS	Allowed	13/768,748	2/15/2013	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	2013205132	4/13/2013	Australia	Utility: Foreign Divisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	2013205139	4/13/2013	Australia	Utility: Foreign Divisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	2013205142	4/13/2013	Australia	Utility: Foreign Divisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	14/183,500	2/18/2014	United States	Utility: Non-Provisional	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SEPARATION MATERIALS	Allowed	14/214,772	3/15/2014	United States	Utility: Non-Provisional	
Nucleic Acid Amplification	Allowed	14/214,850	3/15/2014	United States	Utility: Non-Provisional	9725760
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	2014109864	4/25/2014	Russian Federation	Utility: Foreign	
Methods for Improving Assays of Biological Samples	Allowed	14/341,422	7/25/2014	United States	Utility: Non-Provisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
UNIFIED DETECTION SYSTEM FOR FLUOROMETRY, LUMINOMETRY AND SPECTROMETRY	Allowed	14/602,189	1/21/2015	United States	Utility: Non-Provisional	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Allowed	705695	3/4/2015	New Zealand	Utility: Foreign Divisional	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Allowed	11201502239U	3/23/2015	Singapore	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Allowed	2015-76583	4/3/2015	Japan	Utility: Foreign Divisional	
Fluidic Medical Devices and Uses Thereof	Allowed	14/727,547	6/1/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	14/859,064	9/18/2015	United States	Utility: Continuation	9719990
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Allowed	10-2015-7027017	9/30/2015	Republic of Korea	Utility: Foreign Divisional	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Allowed	14762285.6	10/5/2015	European Patent Office	Utility: Foreign	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Allowed	15/002,013	1/20/2016	United States	Utility: Continuation	9719081
REAL-TIME DETECTION OF INFLUENZA VIRUS	Allowed	10-2016-7005331	2/26/2016	Republic of Korea	Utility: Divisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Allowed	15/162,038	5/23/2016	United States	Utility: Continuation	
BLOOD COLLECTION DEVICE	Allowed	29/568,083	6/15/2016	United States	Design	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Allowed	10-2016-7017039	6/24/2016	Republic of Korea	Utility: Divisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Allowed	201410452665.6	9/5/2014	China	Utility: Foreign Divisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Germany	Utility: Foreign	60 2008 049 418.7

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			France	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			United Kingdom	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Switzerland	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Denmark	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Finland	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Ireland	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Netherlands	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Norway	Utility: Foreign	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued			Sweden	Utility: Foreign	2657699
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Germany	Utility: Foreign	60 2012 029 044.7
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			France	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			United Kingdom	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Belgium	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Switzerland	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Denmark	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Spain	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Finland	Utility: Foreign	2761488

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Ireland	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Italy	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Netherlands	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Norway	Utility: Foreign	2761488
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued			Sweden	Utility: Foreign	2761488
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	10/937,872	9/10/2004	United States	Utility: Non- Provisional	7291497
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	European Patent Office	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Germany	Utility: Foreign	60 2004 035 271.3
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	France	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	United Kingdom	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Austria	Utility: Foreign	1662987
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MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Denmark	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Spain	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Finland	Utility: Foreign	1662987

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Greece	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Hungary	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Ireland	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Italy	Utility: Foreign	48024BE2012
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Luxembourg	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Monaco	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Netherlands	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Portugal	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Sweden	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Turkey	Utility: Foreign	TR201200102T4
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2004272062	9/10/2004	Australia	Utility: Foreign	2004272062
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2010241506	9/10/2004	Australia	Utility: Foreign	2010241506
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2538038	9/10/2004	Canada	Utility: Foreign	2538038
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	780016504	5/10/2007	China	Utility: Foreign	101437550
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	174103	9/10/2004	Israel	Utility: Foreign	174103
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	1291/DELNP/06	9/10/2004	India	Utility: Foreign	239950
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2006-526288	9/10/2004	Japan	Utility: Foreign	4603547



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2010-96515	9/10/2004	Japan	Utility: Foreign Divisional	5255594
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2012-179402	9/10/2004	Japan	Utility: Foreign Divisional	5635041
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	10-06-7006816	9/10/2004	Republic of Korea	Utility: Foreign	1330431
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	10-2012-7008407	9/10/2004	Republic of Korea	Utility: Foreign	1328849
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	10-2012-7022103	9/10/2004	Republic of Korea	Utility: Foreign Divisional	1471731
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	10-2012-7032495	9/10/2004	Republic of Korea	Utility: Foreign Divisional	1496392
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	546432	9/10/2004	New Zealand	Utility: Foreign	546432
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	580449	9/10/2004	New Zealand	Utility: Foreign	580449
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	0 478 8658.5	9/10/2004	Poland	Utility: Foreign	1662987
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	11/202,206	8/12/2005	United States	Utility: Non-Provisional	8101402
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	11/202,231	8/12/2005	United States	Utility: Non-Provisional	8202697
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	11/389,409	3/24/2006	United States	Utility: Non-Provisional	7635594
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	2006244617	3/24/2006	Australia	Utility: Foreign	2006244617
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	2013201509	3/24/2006	Australia	Utility: Foreign Divisional	2013201509

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	200780037859.8	10/10/2007	China	Utility: Foreign	ZL 200780037859.8
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	187272	3/24/2006	Israel	Utility: Foreign	187272
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	2007-7028881	3/24/2006	Republic of Korea	Utility: Foreign	1381331
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	10-2013-7005225	3/24/2006	Republic of Korea	Utility: Foreign	1392106
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	10-2013-7027526	3/24/2006	Republic of Korea	Utility: Foreign Divisional	1569265
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	a/2007/013985	3/24/2006	Mexico	Utility: Foreign	309006
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	a/2013/001275	3/24/2006	Mexico	Utility: Foreign Divisional	322934
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	a/2013/001320	3/24/2006	Mexico	Utility: Foreign Divisional	332010
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	564141	3/24/2006	New Zealand	Utility: Foreign	564141
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	590930	3/24/2006	New Zealand	Utility: Foreign	590930
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	599522	3/24/2006	New Zealand	Utility: Foreign	599522
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	603604	3/24/2006	New Zealand	Utility: Foreign	603604
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	603613	3/24/2006	New Zealand	Utility: Foreign	603613
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	620811	3/24/2006	New Zealand	Utility: Foreign Divisional	620811
Systems and methods for improving medical treatments	Issued	11/388,415	3/24/2006	United States	Utility: Non-Provisional	8679407



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR CONDUCTING ANIMAL STUDIES	Issued	11/388,823	3/24/2006	United States	Utility: Non-Provisional	8841076
CALIBRATION OF FLUIDIC DEVICES	Issued	11/388,824	3/24/2006	United States	Utility: Non-Provisional	7888125
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	11/549,558	10/13/2006	United States	Utility: Non-Provisional	8012744
Systems and Methods of Sample Processing and Fluid Control in a Fluidic System	Issued	11/554,509	10/30/2006	United States	Utility: Non-Provisional	8741230
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	11/685,615	3/13/2007	United States	Utility: Non-Provisional	8008034
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11/746,535	5/9/2007	United States	Utility: Non-Provisional	8007999
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	European Patent Office	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	European Patent Office	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Germany	Utility: Foreign	602007031274.4
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Germany	Utility: Foreign	60 2007 037 520.7
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	France	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	France	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	United Kingdom	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	United Kingdom	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Belgium	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Belgium	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Switzerland	Utility: Foreign	2018188

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<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Switzerland	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Denmark	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Spain	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Spain	Utility: Foreign	2493265
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Ireland	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Ireland	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Italy	Utility: Foreign	51305 BE 2013
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Italy	Utility: Foreign	50201400000077 1
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Luxembourg	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Netherlands	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Netherlands	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Sweden	Utility: Foreign	2018188
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	11180769.9	5/10/2007	Sweden	Utility: Foreign	2436400
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	7762092	5/10/2007	Turkey	Utility: Foreign	TR 2013 10950 T4
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	2007249334	5/10/2007	Australia	Utility: Foreign	2007249334
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	200880118646.2	10/2/2008	China	Utility: Foreign	200880118646.2
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	200980119929.3	3/26/2009	China	Utility: Foreign	200980119929.3

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<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	195108	5/10/2007	Israel	Utility: Foreign	195108
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	9081/DELNP/08	5/10/2007	India	Utility: Foreign	269876
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	2009-510174	5/10/2007	Japan	Utility: Foreign	4856759
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	2011-237908	5/10/2007	Japan	Utility: Foreign	5575088
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	2013-247236	5/10/2007	Japan	Utility: Foreign Divisional	5916693
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	10-2008-7028354	5/10/2007	Republic of Korea	Utility: Foreign	1397879
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	a/2008/014224	5/10/2007	Mexico	Utility: Foreign	297386
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	MX/a/2012/0033 67	5/10/2007	Mexico	Utility: Foreign Divisional	321606
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	572480	5/10/2007	New Zealand	Utility: Foreign	572480
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	9104140.2	5/10/2007	Hong Kong	Utility: Foreign	1127279B
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	12109767.8	5/10/2007	Hong Kong	Utility: Foreign	1170149
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	European Patent Office	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Germany	Utility: Foreign	602007048147.3
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	France	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Italy	Utility: Foreign	50201600011319 1
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	United Kingdom	Utility: Foreign	2066777

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<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Belgium	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Switzerland	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Denmark	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Spain	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Ireland	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Netherlands	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	7868405.7	10/10/2007	Sweden	Utility: Foreign	2066777
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2007324129	10/10/2007	Australia	Utility: Foreign	2007324129
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	201280014347.0	1/20/2012	China	Utility: Foreign	ZL201280014347.0
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	198113	10/10/2007	Israel	Utility: Foreign	198113
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	227945	10/10/2007	Israel	Utility: Foreign Divisional	227945
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2009-532550	10/10/2007	Japan	Utility: Foreign	5373614
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2013-37058	10/10/2007	Japan	Utility: Foreign	5773456
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2009-7009660	10/10/2007	Republic of Korea	Utility: Foreign	1445409
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	a/2009/003572	10/10/2007	Mexico	Utility: Foreign	302441
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	576116	10/10/2007	New Zealand	Utility: Foreign	576116

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	9111657.2	10/10/2007	Hong Kong	Utility: Foreign	9111657.2
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	10-2011-7006832	12/10/2007	Republic of Korea	Utility: Foreign Divisional	1322943
SYSTEMS AND METHODS OF FLUIDIC SAMPLE PROCESSING	Issued	12/221,816	8/6/2008	United States	Utility: Non-Provisional	8158430
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	12/244,723	10/2/2008	United States	Utility: Non-Provisional	8088593
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	European Patent Office	Utility: Foreign	2205968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	13178059.5	10/2/2008	European Patent Office	Utility: Foreign Divisional	2657699
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Germany	Utility: Foreign	60 2008 028 891.9
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	France	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	United Kingdom	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Switzerland	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Denmark	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Spain	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Ireland	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Italy	Utility: Foreign	67746 BE 2014
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Netherlands	Utility: Foreign	2 205 968
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	8836072.2	10/2/2008	Sweden	Utility: Foreign	2 205 968

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	2008308686	10/2/2008	Australia	Utility: Foreign	2008308686
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	2013205052	10/2/2008	Australia	Utility: Foreign Divisional	2013205052
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	204877	10/2/2008	Israel	Utility: Foreign	204877
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	223603	10/2/2008	Israel	Utility: Foreign Divisional	223603
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	223599	10/2/2008	Israel	Utility: Foreign Divisional	223599
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	223600	10/2/2008	Israel	Utility: Foreign Divisional	223600
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	223602	10/2/2008	Israel	Utility: Foreign Divisional	223602
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	2010-528139	10/2/2008	Japan	Utility: Foreign	5511669
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	2010-7009627	10/2/2008	Republic of Korea	Utility: Foreign	1579327
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	10-2013-7025985	10/2/2008	Republic of Korea	Utility: Foreign Divisional	1669323
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	a/2010/003578	10/2/2008	Mexico	Utility: Foreign	303109
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	a/2012/004302	10/2/2008	Mexico	Utility: Foreign	316656
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	a/2013/012110	10/2/2008	Mexico	Utility: Foreign Divisional	328161

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	584963	10/2/2008	New Zealand	Utility: Foreign	584963
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	2010117267	10/2/2008	Russian Federation	Utility: Foreign	2540424
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	201002319-0	10/2/2008	Singapore	Utility: Foreign	160604
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	201300584-8	10/2/2008	Singapore	Utility: Foreign Divisional	188082
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	11104252.2	10/2/2008	Hong Kong	Utility: Foreign	HK1150175
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	2009228145	3/26/2009	Australia	Utility: Foreign	2009228145
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	201310053649.5	5/10/2007	China	Utility: Foreign	CN 103197064 B
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	208323	3/26/2009	Israel	Utility: Foreign	208323
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	2011-502079	3/26/2009	Japan	Utility: Foreign	5550633
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	588741	3/26/2009	New Zealand	Utility: Foreign	588741
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	2010006966-4	3/26/2009	Singapore	Utility: Foreign	164988
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	201109703-7	3/26/2009	Singapore	Utility: Foreign Divisional	177936
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	201109708-6	3/26/2009	Singapore	Utility: Foreign Divisional	177937
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	12/576,197	10/8/2009	United States	Utility: Non-Provisional	8283155
Fluidic Medical Devices and Uses Thereof	Issued	12/625,430	11/24/2009	United States	Utility: Continuation	9075046

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
DETECTION AND QUANTIFICATION OF ANALYTES IN BODILY FLUIDS	Issued	12/750,518	3/30/2010	United States	Utility: Continuation	8778665
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	12/906,975	10/18/2010	United States	Utility: Non-Provisional	8862448
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	2010308329	10/18/2010	Australia	Utility: Foreign	2010308329
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	219324	10/18/2010	Israel	Utility: Foreign	219324
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	2012-53283	10/18/2010	Japan	Utility: Foreign	5743288
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	MX/a/2012/004620	10/18/2010	Mexico	Utility: Foreign	324592
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	599873	10/18/2010	New Zealand	Utility: Foreign	599873
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	201202826-2	10/18/2010	Singapore	Utility: Foreign	180421
CALIBRATION OF FLUIDIC DEVICES	Issued	12/986,954	1/7/2011	United States	Utility: Non-Provisional	9182388
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	13/049,813	3/16/2011	United States	Utility: Non-Provisional	9131884
Real-Time Detection of Influenza Virus	Issued	13/187,960	7/21/2011	United States	Utility: Non-Provisional	8669047
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	13/188,288	7/21/2011	United States	Utility: Non-Provisional	8470524
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	13/244,762	9/26/2011	United States	Utility: Non-Provisional	8265955
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	13/244,947	9/26/2011	United States	Utility: Non-Provisional	8435738
Systems and methods for multi-purpose analysis	Issued	13/244,949	9/26/2011	United States	Utility: Non-Provisional	9632102
SYSTEMS AND METHODS FOR DIAGNOSIS OR TREATMENT	Issued	13/244,956	9/26/2011	United States	Utility: Non-Provisional	9268915
SYSTEMS AND METHODS FOR FLUID HANDLING	Issued	13/244,952	9/26/2011	United States	Utility: Non-Provisional	8475739

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
FLUID HANDLING APPARATUS AND CONFIGURATIONS	Issued	13/244,950	9/26/2011	United States	Utility: Non-Provisional	9664702
CENTRIFUGE CONFIGURATIONS	Issued	13/244,954	9/26/2011	United States	Utility: Non-Provisional	8840838
METHODS AND SYSTEMS FOR FACILITATING NETWORK CONNECTIVITY	Issued	13/244,836	9/26/2011	United States	Utility: Non-Provisional	8392585
SYSTEMS AND METHODS FOR COLLECTING AND TRANSMITTING ASSAY RESULTS	Issued	13/244,946	9/26/2011	United States	Utility: Non-Provisional	8380541
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	13/326,023	12/14/2011	United States	Utility: Continuation	9435793
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	2012207090	1/20/2012	Australia	Utility: Foreign	2012207090
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	2013-550651	1/20/2012	Japan	Utility: Foreign	5945282
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	MX/a/2013/008339	1/20/2012	Mexico	Utility: Foreign	334513
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	613457	1/20/2012	New Zealand	Utility: Foreign	613457
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	201305560-3	1/20/2012	Singapore	Utility: Foreign	192069
SYSTEMS AND METHODS OF FLUIDIC SAMPLE PROCESSING	Issued	13/436,568	3/30/2012	United States	Utility: Non-Provisional	8883518
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	600177	5/23/2012	New Zealand	Utility: Foreign	600177
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2012213965	8/15/2012	Australia	Utility: Foreign Divisional	2012213965
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	13/609,144	9/10/2012	United States	Utility: Non-Provisional	8538774
Methods and Systems for Network Connectivity	Issued	13/764,642	2/11/2013	United States	Utility: Non-Provisional	8862750
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	13/769,779	2/18/2013	United States	Utility: Non-Provisional	9250229

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
Systems and Methods for Collecting and Transmitting Assay Results	Issued	13/769,798	2/18/2013	United States	Utility: Non-Provisional	9619627
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued	13/784,814	3/4/2013	United States	Utility: Continuation -in-Part	9596156
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	2013205047	4/13/2013	Australia	Utility: Foreign Divisional	2013205047
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	2013205019	4/13/2013	Australia	Utility: Foreign Divisional	2013205019
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	2013205020	4/13/2013	Australia	Utility: Foreign Divisional	2013205020
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	13/889,674	5/8/2013	United States	Utility: Continuation	8822167
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	13/893,258	5/13/2013	United States	Utility: Continuation	9121851
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	13/916,553	6/12/2013	United States	Utility: Continuation	8697377
SYSTEMS AND METHODS FOR FLUID HANDLING	Issued	13/933,035	7/1/2013	United States	Utility: Continuation	9592508
METHODS FOR DETECTING AND MEASURING AGGREGATION	Issued	13/944,857	7/17/2013	United States	Utility: Non-Provisional	9389229
LOW-VOLUME COAGULATION ASSAY	Issued	13/944,863	7/17/2013	United States	Utility: Non-Provisional	9500639
Rapid Measurement of Formed Blood Component Sedimentation Rate from Small Sample Volumes	Issued	13/945,147	7/18/2013	United States	Utility: Non-Provisional	9347867
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Issued	13/951,063	7/25/2013	United States	Utility: Non-Provisional	9494521
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Issued	13/951,449	7/25/2013	United States	Utility: Non-Provisional	9395302

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	614566	8/21/2013	New Zealand	Utility: Foreign Divisional	614566
SAMPLE CONTAINER	Issued	29/466,413	9/6/2013	United States	Design	D748279
SAMPLE CONTAINER	Issued	29/466,415	9/6/2013	United States	Design	D754361
Blood Collection Device	Issued	29/466,434	9/8/2013	United States	Design	D746976
Blood Collection Device	Issued	29/466,436	9/8/2013	United States	Design	D745662
Blood Collection Device	Issued	29/466,437	9/8/2013	United States	Design	D745663
VENOUS BLOOD COLLECTION DEVICE	Issued	29/466,438	9/8/2013	United States	Design	D744089
VENOUS BLOOD COLLECTION DEVICE	Issued	29/466,439	9/8/2013	United States	Design	D743024
Shipping Container	Issued	29/466,440	9/8/2013	United States	Design	D732686
SHIPPING CONTAINER	Issued	29/466,441	9/8/2013	United States	Design	D733314
Shipping Container	Issued	29/466,442	9/8/2013	United States	Design	D733315
Shipping Container	Issued	29/466,443	9/8/2013	United States	Design	D733316
SHIPPING CONTAINER	Issued	29/466,710	9/10/2013	United States	Design	D733317
BLOOD COLLECTION DEVICE	Issued	29/466,709	9/10/2013	United States	Design	D729379
SHIPPING CONTAINER	Issued	29/466,739	9/11/2013	United States	Design	D733318
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	2013231105	9/20/2013	Australia	Utility: Foreign Divisional	2013231105
FINGER WARMER	Issued	29/467,883	9/24/2013	United States	Design	D719302
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	616116	9/30/2013	New Zealand	Utility: Foreign Divisional	616116
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2013267006	12/4/2013	Australia	Utility: Foreign Divisional	2013267006
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE TRANSPORT	Issued	14/098,177	12/5/2013	United States	Utility: Non-Provisional	9386948
RAPID, LOW-SAMPLE-VOLUME CHOLESTEROL AND TRIGLYCERIDE ASSAYS	Issued	14/100,870	12/9/2013	United States	Utility: Non-Provisional	9051599

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	10-2013-7032653	12/9/2013	Republic of Korea	Utility: Foreign Divisional	1556457
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	2013270537	12/12/2013	Australia	Utility: Foreign Divisional	2013270537
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	10-2013-7033688	12/18/2013	Republic of Korea	Utility: Foreign Divisional	1476089
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	13114296.7	12/26/2013	Hong Kong	Utility: Foreign	HK1186774
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	MX/a/2014/000377	1/9/2014	Mexico	Utility: Foreign Divisional	327455
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Issued	14/161,639	1/22/2014	United States	Utility: Non-Provisional	9513224
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	2014-38435	2/28/2014	Japan	Utility: Foreign Divisional	5864642
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	622186	3/7/2014	New Zealand	Utility: Foreign	622186
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Issued	14/203,436	3/10/2014	United States	Utility: Non-Provisional	9359632
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	MX/a/2014/002991	3/13/2014	Mexico	Utility: Foreign	344792
SYSTEMS, DEVICES, AND METHODS FOR INTEGRATED PATIENT SERVICE CENTER	Issued	14/214,599	3/14/2014	United States	Utility: Non-Provisional	9538992
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Issued	14/214,774	3/15/2014	United States	Utility: Non-Provisional	9636062
Nucleic Acid Amplification	Issued	14/214,848	3/15/2014	United States	Utility: Non-Provisional	9416387
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Issued	14/214,834	3/15/2014	United States	Utility: Non-Provisional	9273301

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	10-2014-7007309	3/19/2014	Republic of Korea	Utility: Foreign Divisional	1474699
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	112014008325	3/20/2014	Singapore	Utility: Foreign	112014008325
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued	12836129.2	4/25/2014	European Patent Office	Utility: Foreign	2761488
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2014-092245	4/28/2014	Japan	Utility: Foreign Divisional	6117733
Systems and Methods of Sample Processing and Fluid Control in a Fluidic System	Issued	14/270,618	5/6/2014	United States	Utility: Non-Provisional	9176126
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	624935	5/13/2014	New Zealand	Utility: Foreign Divisional	624935
Detection and Quantification of Analytes in Bodily Fluids	Issued	14/285,562	5/22/2014	United States	Utility: Non-Provisional	9303286
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2852974	5/30/2014	Canada	Utility: Foreign Divisional	2852974
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2014-121153	6/12/2014	Japan	Utility: Foreign Divisional	5936283
METHODS AND DEVICES FOR SMALL VOLUME LIQUID CONTAINMENT	Issued	14/309,877	6/19/2014	United States	Utility: Non-Provisional	9623411
METHODS AND DEVICES FOR SAMPLE ANALYSIS	Issued	14/309,888	6/19/2014	United States	Utility: Non-Provisional	9562860
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	10-2014-7017496	6/25/2014	Republic of Korea	Utility: Foreign Divisional	1633569
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Issued	14/319,644	6/30/2014	United States	Utility: Continuation -in-Part	8984932

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Issued	14/320,471	6/30/2014	United States	Utility: Continuation -in-Part	9427184
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	627239	7/9/2014	New Zealand	Utility: Foreign Divisional	627239
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	10-2014-7019652	7/15/2014	Republic of Korea	Utility: Foreign Divisional	1569307
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	233706	7/17/2014	Israel	Utility: Foreign Divisional	233706
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	14/339,946	7/24/2014	United States	Utility: Continuation	9012163
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	10-2014-7022864	8/14/2014	Republic of Korea	Utility: Foreign Divisional	1532528
SYSTEMS AND METHODS for DETECTING INFECTIOUS DISEASES	Issued	14/479,241	9/5/2014	United States	Utility: Non-Provisional	9529976
SYSTEMS AND METHODS for DETECTING INFECTIOUS DISEASES	Issued	14/479,245	9/5/2014	United States	Utility: Non-Provisional	9460268
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Issued	14/479,190	9/5/2014	United States	Utility: Non-Provisional	9302264
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	234496	9/7/2014	Israel	Utility: Foreign Divisional	234496
CENTRIFUGE CONFIGURATIONS	Issued	14/480,960	9/9/2014	United States	Utility: Divisional	9128015
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	14/511,753	10/10/2014	United States	Utility: Continuation	9460263
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	MX/a/2014/012562	10/17/2014	Mexico	Utility: Divisional	344735
SYSTEMS AND METHODS OF FLUIDIC SAMPLE PROCESSING	Issued	14/534,064	11/5/2014	United States	Utility: Continuation	9575058

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
FINGER WARMER	Issued	29/508,576	11/7/2014	United States	Design	D765920
Nucleic Acid Amplification	Issued	14/546,998	11/18/2014	United States	Utility: Continuation	9551027
REAL-TIME DETECTION OF INFLUENZA VIRUS	Issued	10-2014- 7032932	11/24/2014	Republic of Korea	Utility: Divisional	1573164
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	10-2014- 7034261	12/5/2014	Republic of Korea	Utility: Foreign Divisional	1593868
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	14/562,066	12/5/2014	United States	Utility: Divisional	9464981
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Issued	11201500349Y	1/16/2015	Singapore	Utility: Foreign	11201500349Y
LOW-VOLUME COAGULATION ASSAY	Issued	11201500346Q	1/16/2015	Singapore	Utility: Foreign	11201500346Q
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Issued	MX/a/2015/0010 60	1/23/2015	Mexico	Utility: Foreign	345757
RAPID, LOW-SAMPLE-VOLUME CHOLESTEROL AND TRIGLYCERIDE ASSAYS	Issued	14/604,538	1/23/2015	United States	Utility: Divisional	9546394
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	MX/a/2015/0013 93	1/29/2015	Mexico	Utility: Divisional	337333
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	MX/a/2015/0025 05	2/25/2015	Mexico	Utility: Divisional	340897
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	10-2015- 7007044	3/19/2015	Republic of Korea	Utility: Divisional	1592838
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	706352	3/25/2015	New Zealand	Utility: Foreign Divisional	706352
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	14/670,200	3/26/2015	United States	Utility: Continuation	9285366
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	MX/a/2015/0039 30	3/26/2015	Mexico	Utility: Foreign Divisional	340077

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Issued	13 834412.2	3/30/2015	European Patent Office	Utility: Foreign	2892496
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	10-2015-7008967	4/7/2015	Republic of Korea	Utility: Foreign Divisional	1637140
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Issued	11201503150X	4/22/2015	Singapore	Utility: Foreign	11201503150X
BLOOD COLLECTION DEVICE	Issued	29/526,557	5/11/2015	United States	Design	D762298
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	10-2015-7013343	5/20/2015	Republic of Korea	Utility: Foreign Divisional	1670621
SHIPPING CONTAINER	Issued	29/528,999	6/2/2015	United States	Design	D748280
SHIPPING CONTAINER	Issued	29/529,095	6/3/2015	United States	Design	D762875
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Issued	239229	6/4/2015	Israel	Utility: Foreign	239229
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	10-2015-7015898	6/15/2015	Republic of Korea	Utility: Foreign Divisional	1702483
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Issued	14/789,967	7/1/2015	United States	Utility: Continuation	9677993
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	MX/a/2015/010496	8/13/2015	Mexico	Utility: Foreign	342267
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	14/831,734	8/20/2015	United States	Utility: Continuation	9581588
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Issued	2015221460	9/1/2015	Australia	Utility: Divisional	2015221460
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Issued	11201507011V	9/3/2015	Singapore	Utility: Foreign	11201507011V
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Issued	MX/a/2015/011773	9/7/2015	Mexico	Utility: Foreign	348826
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	2015-175649	9/7/2015	Japan	Utility: Foreign Divisional	6139616

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Issued	14/849,264	9/9/2015	United States	Utility: Continuation	9515618
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Issued	241429	9/10/2015	Israel	Utility: Foreign	241429
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Issued	712746	9/25/2015	New Zealand	Utility: Foreign Divisional	712746
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Issued	14/872,919	10/1/2015	United States	Utility: Continuation	9645143
VENOUS BLOOD COLLECTION DEVICE	Issued	29/544,315	11/2/2015	United States	Design	D784517
FINGER WARMER	Issued	29/545,319	11/11/2015	United States	Design	D775428
Blood Collection Device	Issued	29/546,672	11/24/2015	United States	Design	D785782
Blood Collection Device	Issued	29/547,195	12/1/2015	United States	Design	D785783
SAMPLE CONTAINER	Issued	29/551,201	1/11/2016	United States	Design	D779081
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Issued	15/007,585	1/27/2016	United States	Utility: Continuation	9588109
METHODS, DEVICES, AND SYSTEMS FOR MIXING FLUIDS	Issued	15/069,263	3/14/2016	United States	Utility: Continuation	9513197
SYSTEMS, DEVICES, AND METHODS FOR INTEGRATED PATIENT SERVICE CENTER	Issued	15/160,936	5/20/2016	United States	Utility: Continuation	9572550
SHIPPING CONTAINER	Issued	29/568,769	6/21/2016	United States	Design	D791964
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	201410446608.7	9/3/2014	China	Utility: Foreign Divisional	201410446608.7
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Issued	200680024658.X	3/24/2006	China	Utility: Foreign	200680024658.X
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Issued	201310170188.X	10/2/2008	China	Utility: Foreign Divisional	ZL201310170188.X
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Issued	CN 0480030548.5	9/10/2004	China	Utility: Foreign	200480030548-5
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Issued	CN 201080057878.9	10/18/2010	China	Utility: Foreign	ZL 2010 8 0057878.9

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	17105363.9	5/29/2017	China	Utility: Foreign	
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Pending	10179887.4	9/10/2004	European Patent Office	Utility: Foreign Divisional	
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Pending	7135/DELNP/09	9/10/2004	India	Utility: Foreign Divisional	
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Pending	HK 11110543.8	9/10/2004	Hong Kong	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending	2610294	3/24/2006	Canada	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending	2012-238759	3/24/2006	Japan	Utility: Foreign Divisional	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Pending	2650455	5/10/2007	Canada	Utility: Foreign	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Pending	a/2012/009292	10/10/2007	Mexico	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	2017-74278	3/26/2008	Japan	Utility: Divisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	PI 0820328-8	10/2/2008	Brazil	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	2701794	10/2/2008	Canada	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	223604	10/2/2008	Israel	Utility: Foreign Divisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	223601	10/2/2008	Israel	Utility: Foreign Divisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	3055/DELNP/10	10/2/2008	India	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	2013127796	10/2/2008	Russian Federation	Utility: Foreign Divisional	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	PI 0910608-1	3/26/2009	Brazil	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	2719625	3/26/2009	Canada	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	2010-7023945	3/26/2009	Republic of Korea	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	a/2010/010400	3/26/2009	Mexico	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	2010143465	3/26/2009	Russian Federation	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	201109710-2	3/26/2009	Singapore	Utility: Foreign Divisional	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	11111058.3	3/26/2009	Hong Kong	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	EP10825481.4	10/18/2010	European Patent Office	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	11 2012 009196-4	10/18/2010	Brazil	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	2778270	10/18/2010	Canada	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	4056/DELNP/2012	10/18/2010	India	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	10-2012-7013027	10/18/2010	Republic of Korea	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	1201001761	10/18/2010	Thailand	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	13103965	10/18/2010	Hong Kong	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	PI2012001739	10/18/2010	Malaysia	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	BR 11 2013 018656-9	1/20/2012	Brazil	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	2825196	1/20/2012	Canada	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	10-2013-7021727	1/20/2012	Republic of Korea	Utility: Foreign	
Systems and Methods for Sample Use Maximization	Pending	101102769	1/20/2012	Taiwan	Utility: Foreign	
Systems and Methods for Multi-Analysis	Pending	101135220	9/25/2012	Taiwan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-PURPOSE ANALYSIS	Pending	20120103532	9/25/2012	Argentina	Utility: Foreign	
METHODS AND SYSTEMS FOR FACILITATING NETWORK CONNECTIVITY	Pending	101135417	9/26/2012	Taiwan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	2849104	3/18/2014	Canada	Utility: Foreign	
METHODS FOR OBTAINING BLOOD FROM A SUBJECT	Pending	14/220,013	3/19/2014	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	BR11 2014 007073-3	3/25/2014	Brazil	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	2014/02984	4/24/2014	South Africa	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	10-2014-7011324	4/25/2014	Republic of Korea	Utility: Foreign	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Pending	10-2014-7011290	4/25/2014	Republic of Korea	Utility: Foreign	
Devices, Systems, and Methods for Cell Analysis in Microgravity	Pending	14/309,689	6/19/2014	United States	Utility: Non-Provisional	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Pending	MX/a/2014/008154	7/2/2014	Mexico	Utility: Continuation	
SYSTEMS AND METHODS FOR LABORATORY TESTING AND RESULTS MANAGEMENT	Pending	14/480,600	9/8/2014	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR LABORATORY TESTING BASED ON MICROVOLUME SAMPLE	Pending	14/480,477	9/8/2014	United States	Utility: Non-Provisional	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR ANALYTE TESTING AND DATA MANAGEMENT	Pending	14/480,405	9/8/2014	United States	Utility: Non-Provisional	
DEVICES, METHODS AND SYSTEMS FOR REDUCING SAMPLE VOLUME	Pending	14/481,858	9/9/2014	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR ANALYTE TESTING AND LABORATORY OVERSIGHT	Pending	14/490,653	9/18/2014	United States	Utility: Non-Provisional	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	11202/DELNP/2014	12/29/2014	India	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	2013292378	1/6/2015	Australia	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	2013292400	1/6/2015	Australia	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	2013295679	1/6/2015	Australia	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	2013292395	1/6/2015	Australia	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Pending	2013292392	1/6/2015	Australia	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	2878872	1/9/2015	Canada	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	2878886	1/9/2015	Canada	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	2878957	1/9/2015	Canada	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	2878880	1/9/2015	Canada	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Pending	2878875	1/9/2015	Canada	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	MX/a/2015/000807	1/16/2015	Mexico	Utility: Foreign	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	BR 11 2015 001075-0	1/16/2015	Brazil	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	MX/a/2015/000814	1/16/2015	Mexico	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	11201500343V	1/16/2015	Singapore	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	11201500347S	1/16/2015	Singapore	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	BR 11 2015 001087-3	1/16/2015	Brazil	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	MX/a/2015/000809	1/16/2015	Mexico	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	11201500344X	1/16/2015	Singapore	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Pending	BR 11 2015 001048-2	1/16/2015	Brazil	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Pending	MX/a/2015/000808	1/16/2015	Mexico	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	236769	1/18/2015	Israel	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	BR 11 2015 001239-6	1/19/2015	Brazil	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	BR 11 2015 001592-1	1/23/2015	Brazil	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2013312306	2/2/2015	Australia	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2881028	2/5/2015	Canada	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2015/00836	2/5/2015	South Africa	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	10-2015-7003471	2/9/2015	Republic of Korea	Utility: Foreign	

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HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	10-2015-7003902	2/13/2015	Republic of Korea	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	2015/01084	2/17/2015	South Africa	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	2015/01085	2/17/2015	South Africa	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	2015/01086	2/17/2015	South Africa	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	10-2015-7004315	2/17/2015	Republic of Korea	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Pending	2015/01087	2/17/2015	South Africa	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Pending	10-2015-7004309	2/17/2015	Republic of Korea	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Pending	2015/01088	2/17/2015	South Africa	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	14/630,544	2/24/2015	United States	Utility: Non-Provisional	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Pending	2013315800	2/24/2015	Australia	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	10-2015-7004737	2/25/2015	Republic of Korea	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE HANDLING	Pending	14/631,830	2/25/2015	United States	Utility: Non-Provisional	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Pending	2883521	2/27/2015	Canada	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	MX/a/2015/002921	3/5/2015	Mexico	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	11201501676Q	3/5/2015	Singapore	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Pending	MX/a/2015/002919	3/5/2015	Mexico	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	BR 11 2015 005028-0	3/6/2015	Brazil	Utility: Foreign	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Pending	2013323790	3/6/2015	Australia	Utility: Foreign	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Pending	2884305	3/6/2015	Canada	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Pending	2015/01622	3/10/2015	South Africa	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Pending	11 2015 005429-3	3/11/2015	Brazil	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	10-2015-7007271	3/23/2015	Republic of Korea	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	2015201617	3/30/2015	Australia	Utility: Foreign Divisional	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	10-2015-7008911	4/7/2015	Republic of Korea	Utility: Foreign Divisional	
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Pending	2013334700	4/7/2015	Australia	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	2013334917	4/7/2015	Australia	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	2887492	4/8/2015	Canada	Utility: Foreign	
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Pending	2887669	4/9/2015	Canada	Utility: Foreign	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Pending	10-2015-7009288	4/10/2015	Republic of Korea	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Pending	10-2015-7009330	4/10/2015	Republic of Korea	Utility: Foreign	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Pending	3189/DELNP/2015	4/15/2015	India	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	2015/02574	4/16/2015	South Africa	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	BR 11 2015 009039-7	4/22/2015	Brazil	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	MX/a/2015/005068	4/22/2015	Mexico	Utility: Foreign	
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Pending	10-2015-7011292	4/29/2015	Republic of Korea	Utility: Foreign	
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Pending	3826/DELNP/2015	5/5/2015	India	Utility: Foreign	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Pending	2891513	5/7/2015	Canada	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION AND TRANSPORT	Pending	2013356680	5/8/2015	Australia	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Pending	2013359422	5/14/2015	Australia	Utility: Foreign	
Methods for Analysis of Small Samples	Pending	14/712,077	5/14/2015	United States	Utility: Non-Provisional	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION AND TRANSPORT	Pending	201503477	5/18/2015	South Africa	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	2015/03483	5/18/2015	South Africa	Utility: Foreign Divisional	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Pending	2891944	5/19/2015	Canada	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	4338/DELNP/2015	5/20/2015	India	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Pending	10-2015-7013619	5/22/2015	Republic of Korea	Utility: Foreign	
Preventive Medicine and Optimizing Health	Pending	14/724,535	5/28/2015	United States	Utility: Non-Provisional	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Pending	11201504233R	5/29/2015	Singapore	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Pending	4746/DELNP/2015	6/1/2015	India	Utility: Foreign	

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Systems, Devices, and Methods for Bodily Fluid Sample Transport	Pending	BR112015012944-7	6/3/2015	Brazil	Utility: Foreign	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Pending	MX/a/2015/007134	6/4/2015	Mexico	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Pending	MX/a/2015/007131	6/5/2015	Mexico	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Pending	11201504455P	6/5/2015	Singapore	Utility: Foreign	
SYSTEMS AND METHODS FOR LABORATORY TESTING AND RESULT MANAGEMENT	Pending	14/736,259	6/10/2015	United States	Utility: Non-Provisional	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION, TRANSPORT, AND HANDLING	Pending	14/737,412	6/11/2015	United States	Utility: Non-Provisional	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	2015123307	6/17/2015	Russian Federation	Utility: Foreign Divisional	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Pending	10-2015-7017793	7/2/2015	Republic of Korea	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Pending	10-2015-7018325	7/8/2015	Republic of Korea	Utility: Foreign	
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Pending	2896407	7/8/2015	Canada	Utility: Foreign Divisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	2014217893	7/9/2015	Australia	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	709904	7/9/2015	New Zealand	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	14/800,647	7/15/2015	United States	Utility: Continuation -in-Part	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	2898477	7/16/2015	Canada	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	2014217946	8/4/2015	Australia	Utility: Foreign	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	710772	8/5/2015	New Zealand	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	2014216060	8/6/2015	Australia	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	710802	8/6/2015	New Zealand	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	1501004514	8/10/2015	Thailand	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	2901052	8/11/2015	Canada	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	2901016	8/11/2015	Canada	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	BR112015019315-3	8/12/2015	Brazil	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	MX/a/2015/010480	8/13/2015	Mexico	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	MX/a/2015/010479	8/13/2015	Mexico	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	11201506351T	8/13/2015	Singapore	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	BR112015019614-4	8/14/2015	Brazil	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	11201506420W	8/14/2015	Singapore	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	1501004674	8/17/2015	Thailand	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	1501004673	8/17/2015	Thailand	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	BR112015019753-1	8/17/2015	Brazil	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	2015/05955	8/18/2015	South Africa	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	2015/05957	8/18/2015	South Africa	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2014232347	8/27/2015	Australia	Utility: Foreign	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Pending	2014225907	8/27/2015	Australia	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	2014237362	8/28/2015	Australia	Utility: Foreign	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Pending	2014233213	8/28/2015	Australia	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	2014233152	8/28/2015	Australia	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	2014233184	8/31/2015	Australia	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	711660	8/31/2015	New Zealand	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	2014233145	8/31/2015	Australia	Utility: Foreign	
Nucleic Acid Amplification	Pending	2014233150	8/31/2015	Australia	Utility: Foreign	
Nucleic Acid Amplification	Pending	711649	8/31/2015	New Zealand	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	2014232375	8/31/2015	Australia	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	711671	8/31/2015	New Zealand	Utility: Foreign	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Pending	2903417	9/1/2015	Canada	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2903839	9/2/2015	Canada	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	MX/a/2015/0114 27	9/2/2015	Mexico	Utility: Foreign	
Nucleic Acid Amplification	Pending	MX/a/2015/0114 35	9/2/2015	Mexico	Utility: Foreign	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Pending	2903873	9/2/2015	Canada	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	MX/a/2015/0114 47	9/2/2015	Mexico	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	2903874	9/2/2015	Canada	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	2014241170	9/2/2015	Australia	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	711792	9/2/2015	New Zealand	Utility: Foreign	
BIOLOGICAL SAMPLE PROCESSING	Pending	2014241182	9/3/2015	Australia	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	MX/a/2015/0117 64	9/7/2015	Mexico	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	11201507127S	9/7/2015	Singapore	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2015/06587	9/7/2015	South Africa	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	2015/06588	9/7/2015	South Africa	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	2015/06596	9/7/2015	South Africa	Utility: Foreign	
Nucleic Acid Amplification	Pending	2015/06593	9/7/2015	South Africa	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	2015/06592	9/7/2015	South Africa	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	2015/06595	9/7/2015	South Africa	Utility: Foreign	
Nucleic Acid Amplification	Pending	11201507272R	9/8/2015	Singapore	Utility: Foreign	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Pending	11201507264Y	9/8/2015	Singapore	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	11201507261W	9/8/2015	Singapore	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	BR112015022167 -0	9/9/2015	Brazil	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	11201507322U	9/9/2015	Singapore	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	11201507325X	9/9/2015	Singapore	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	1501005234	9/9/2015	Thailand	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	11201507315T	9/9/2015	Singapore	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	1501005235	9/9/2015	Thailand	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	1501005288	9/10/2015	Thailand	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	8290/DELNP/2015	9/11/2015	India	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	BR112015022738-4	9/11/2015	Brazil	Utility: Foreign	
Nucleic Acid Amplification	Pending	1501005395	9/11/2015	Thailand	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	BR112015022658-2	9/11/2015	Brazil	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	2906230	9/11/2015	Canada	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	1501005396	9/11/2015	Thailand	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	2014257185	9/11/2015	Australia	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	712222	9/11/2015	New Zealand	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	BR112015023338-4	9/14/2015	Brazil	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	2906484	9/14/2015	Canada	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	1501005503	9/14/2015	Thailand	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	2906810	9/14/2015	Canada	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	2906824	9/14/2015	Canada	Utility: Foreign	
Nucleic Acid Amplification	Pending	BR112015023398-8	9/14/2015	Brazil	Utility: Foreign	
Nucleic Acid Amplification	Pending	2906805	9/14/2015	Canada	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	10-2015-7025314	9/15/2015	Republic of Korea	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	2015/06824	9/15/2015	South Africa	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	2907504	9/15/2015	Canada	Utility: Foreign	
BIOLOGICAL SAMPLE PROCESSING	Pending	2907506	9/15/2015	Canada	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	2015/06827	9/15/2015	South Africa	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	10-2015-7025437	9/16/2015	Republic of Korea	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	10-2015-7025660	9/17/2015	Republic of Korea	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	BR112015024266-9	9/21/2015	Brazil	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	2907778	9/21/2015	Canada	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	MX/a/2015/013596	9/24/2015	Mexico	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	11201507967W	9/25/2015	Singapore	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending	2015234373	10/2/2015	Australia	Utility: Foreign Divisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	9163/DELNP/2015	10/5/2015	India	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	9159/DELNP/2015	10/5/2015	India	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	9230/DELNP/2015	10/6/2015	India	Utility: Foreign	
Nucleic Acid Amplification	Pending	9229/DELNP/2015	10/6/2015	India	Utility: Foreign	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Pending	9225/DELNP/2015	10/6/2015	India	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	10-2015-7027838	10/7/2015	Republic of Korea	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	9354/DELNP/2015	10/8/2015	India	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Pending	9438/DELNP/2015	10/9/2015	India	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	9448/DELNP/2015	10/10/2015	India	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	10-2015-7028425	10/12/2015	Republic of Korea	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	10-2015-7029367	10/14/2015	Republic of Korea	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	10-2015-7029693	10/15/2015	Republic of Korea	Utility: Foreign	
Nucleic Acid Amplification	Pending	10-2015-7029640	10/15/2015	Republic of Korea	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	10-2015-7030214	10/15/2015	Republic of Korea	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	MX/a/2015/014545	10/15/2015	Mexico	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	1501006348	10/15/2015	Thailand	Utility: Foreign	

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MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Pending	2015243036	10/15/2015	Australia	Utility: Foreign Divisional	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	9834/DELNP/2015	10/19/2015	India	Utility: Foreign	
BIOLOGICAL SAMPLE PROCESSING	Pending	9835/DELNP/2015	10/19/2015	India	Utility: Foreign	
Sample Processing Device	Pending	29/543,206	10/21/2015	United States	Design	
Sample Processing Device	Pending	29/543,207	10/21/2015	United States	Design	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	BR112015026896	10/22/2015	Brazil	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	MX/a/2015/015131	10/29/2015	Mexico	Utility: Foreign Divisional	
SYSTEMS AND METHODS FOR MOBILE SAMPLE COLLECTION	Pending	14/936,599	11/9/2015	United States	Utility: Non-Provisional	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	10551/DELNP/2015	11/17/2015	India	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Pending	10-2015-7033256	11/20/2015	Republic of Korea	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	715656	1/5/2016	New Zealand	Utility: Divisional	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	2014292858	1/8/2016	Australia	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	2917917	1/8/2016	Canada	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	201617001027	1/11/2016	India	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	BR112016001469-3	1/22/2016	Brazil	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	MX/a/2016/001077	1/22/2016	Mexico	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	11201600568Q	1/25/2016	Singapore	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	2016/00530	1/25/2016	South Africa	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	2014317990	2/4/2016	Australia	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	2014317986	2/8/2016	Australia	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	2920896	2/9/2016	Canada	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Pending	2014317896	2/10/2016	Australia	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	2921226	2/11/2016	Canada	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Pending	2921679	2/17/2016	Canada	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	2016201032	2/19/2016	Australia	Utility: Divisional	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	201617006316	2/23/2016	India	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	10-2016-7004899	2/24/2016	Republic of Korea	Utility: Foreign	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Pending	2016201142	2/24/2016	Australia	Utility: Divisional	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	MX/a/2016/0024 22	2/25/2016	Mexico	Utility: Divisional	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	2016/01411	3/1/2016	South Africa	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Pending	2016/01417	3/1/2016	South Africa	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	2016/01415	3/1/2016	South Africa	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	11201601608T	3/2/2016	Singapore	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	MX/a/2016/0028 55	3/3/2016	Mexico	Utility: Foreign	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	11201601611W	3/3/2016	Singapore	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Pending	MX/a/2016/0028 51	3/3/2016	Mexico	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	MX/a/2016/0027 97	3/3/2016	Mexico	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	BR112016004955 -1	3/4/2016	Brazil	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	BR112016004994 -2	3/7/2016	Brazil	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Pending	BR112016005112 -2	3/8/2016	Brazil	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Pending	11201601772S	3/8/2016	Singapore	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	10-2016- 7008744	4/1/2016	Republic of Korea	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	2016202045	4/1/2016	Australia	Utility: Divisional	
Methods and Systems for Obtaining Clinical Samples	Pending	10-2016- 7008932	4/5/2016	Republic of Korea	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Pending	10-2016- 7009078	4/6/2016	Republic of Korea	Utility: Foreign	
Nucleic Acid Amplification	Pending	2014353462	4/11/2016	Australia	Utility: Foreign	
Nucleic Acid Amplification	Pending	2927315	4/13/2016	Canada	Utility: Foreign	
SYSTEMS AND METHODS FOR ORDERING LABORATORY TESTS AND PROVIDING RESULTS THEREOF	Pending	2927938	4/18/2016	Canada	Utility: Foreign	
Sample Processing Device	Pending	3080597	4/21/2016	European Union Trademark and Designs Office	Design	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
Nucleic Acid Amplification	Pending	2016/02978	5/4/2016	South Africa	Utility: Foreign	
Nucleic Acid Amplification	Pending	11201603818Y	5/12/2016	Singapore	Utility: Foreign	
Nucleic Acid Amplification	Pending	MX/a/2016/0066 02	5/20/2016	Mexico	Utility: Foreign	
UNIFIED DETECTION SYSTEM FOR FLUOROMETRY, LUMINOMETRY AND SPECTROMETRY	Pending	15/160,900	5/20/2016	United States	Utility: Continuation	
Nucleic Acid Amplification	Pending	BR 11 2016 011692-5	5/23/2016	Brazil	Utility: Foreign	
Nucleic Acid Amplification	Pending	10-2016- 7013498	5/23/2016	Republic of Korea	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE ANALYSIS	Pending	15/161,650	5/23/2016	United States	Utility: Continuation	
DEVICES, METHODS AND SYSTEMS FOR REDUCING SAMPLE VOLUME	Pending	15/161,859	5/23/2016	United States	Utility: Continuation	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	2016204212	6/20/2016	Australia	Utility: Divisional	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending	MX/a/2016/0084 46	6/23/2016	Mexico	Utility: Divisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	2934220	6/27/2016	Canada	Utility: Divisional	
Systems and Methods for Assay Processing	Pending	15/200,776	7/1/2016	United States	Utility: Non- Provisional	
Systems and Methods for Perform Room Sample Processing	Pending	15/204,962	7/7/2016	United States	Utility: Non- Provisional	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	2936828	7/13/2016	Canada	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	2937060	7/15/2016	Canada	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Pending	MX/a/2016/0095 16	7/21/2016	Mexico	Utility: Foreign	



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HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	MX/a/2016/009484	7/21/2016	Mexico	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	MX/a/2016/009886	7/28/2016	Mexico	Utility: Divisional	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	62/368,854	7/29/2016	United States	Utility: Provisional	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	62/368,864	7/29/2016	United States	Utility: Provisional	
HYBRID MULTI-STEP NUCLEIC ACID AMPLIFICATION	Pending	62/368,904	7/29/2016	United States	Utility: Provisional	
SYSTEMS, METHODS, AND COMPOSITIONS FOR PERFORMING ASSAYS ON BIOLOGICAL SAMPLES	Pending	62/368,761	7/29/2016	United States	Utility: Provisional	
METHODS AND COMPOSITIONS FOR DETECTION OF ZIKA VIRAL INFECTIONS	Pending	62/369,009	7/29/2016	United States	Utility: Provisional	
METHODS AND COMPOSITIONS FOR DETECTION OF ZIKA VIRAL INFECTIONS	Pending	62/369,013	7/29/2016	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	62/368,631	7/29/2016	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	62/368,641	7/29/2016	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	62/368,961	7/29/2016	United States	Utility: Provisional	
Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/368,994	7/29/2016	United States	Utility: Provisional	
Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/368,995	7/29/2016	United States	Utility: Provisional	
Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/369,006	7/29/2016	United States	Utility: Provisional	
Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/369,179	7/31/2016	United States	Utility: Provisional	
Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/369,178	7/31/2016	United States	Utility: Provisional	
Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/369,133	7/31/2016	United States	Utility: Provisional	

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Technologies, Reagents, and Assays for Small-Volume Samples	Pending	62/369,135	7/31/2016	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS AND MANUFACTURING	Pending	62/369,189	7/31/2016	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	62/369,194	7/31/2016	United States	Utility: Provisional	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Pending	2939595	8/11/2016	Canada	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	723167	8/11/2016	New Zealand	Utility: Divisional	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Pending	MX/a/2016/011059	8/24/2016	Mexico	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	2941009	8/26/2016	Canada	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	2941137	8/29/2016	Canada	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Pending	MX/a/2016/011474	9/2/2016	Mexico	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	MX/a/2016/011633	9/8/2016	Mexico	Utility: Foreign	
Methods and Systems for Cooperative Workspace Configuration	Pending	15/265,829	9/14/2016	United States	Utility: Non-Provisional	
Methods, Reagents, Devices, and Systems for Assessing and Determining Solution Stability	Pending	62/396,913	9/20/2016	United States	Utility: Provisional	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Pending	MX/a/2016/012289	9/22/2016	Mexico	Utility: Divisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	MX/a/2016/012281	9/22/2016	Mexico	Utility: Divisional	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Pending	16193325.4	10/11/2016	European Patent Office	Utility: Divisional	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Pending	15/292,063	10/12/2016	United States	Utility: Non-Provisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Pending	10-2016-7029179	10/19/2016	Republic of Korea	Utility: Divisional	



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INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	2016247105	10/19/2016	Australia	Utility: Divisional	
Methods and Systems for Obtaining Clinical Samples	Pending	16112075.5	10/20/2016	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	62/417,263	11/3/2016	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	62/417,267	11/3/2016	United States	Utility: Provisional	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Pending	16112792.7	11/7/2016	Hong Kong	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	2951558	12/7/2016	Canada	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Pending	MX/a/2016/016234	12/8/2016	Mexico	Utility: Foreign	
Devices and Methods for use with a Sample Container	Pending	2951696	12/8/2016	Canada	Utility: Foreign	
Devices and Methods for use with a Sample Container	Pending	MX/a/2016/016232	12/8/2016	Mexico	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	MX/a/2017/000062	1/4/2017	Mexico	Utility: Divisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	17100094.6	1/4/2017	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	MX/a/2017/000226	1/5/2017	Mexico	Utility: Divisional	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Pending	17100185.6	1/6/2017	Hong Kong	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR INTEGRATED PATIENT SERVICE CENTER	Pending	15/404,361	1/12/2017	United States	Utility: Continuation	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	62/449,543	1/23/2017	United States	Utility: Provisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	17100973.2	1/25/2017	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Pending	17100995.6	1/26/2017	Hong Kong	Utility: Foreign	

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Methods and Systems for Obtaining Clinical Samples	Pending	17100994.7	1/26/2017	Hong Kong	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Pending	17100976.9	1/26/2017	Hong Kong	Utility: Foreign	
METHODS AND DEVICES FOR IMPROVED SIGNAL DETECTION FROM BIOLOGICAL SAMPLES	Pending	62/452,949	1/31/2017	United States	Utility: Provisional	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Pending	15/429,551	2/10/2017	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR FLUID HANDLING	Pending	15/430,197	2/10/2017	United States	Utility: Continuation	
SYSTEMS AND METHODS for DETECTING INFECTIOUS DISEASES	Pending	17101971.2	2/22/2017	Hong Kong	Utility: Foreign	
METHODS AND SYSTEMS FOR A SAMPLE COLLECTION DEVICE WITH A NOVELTY EXTERIOR	Pending	17101969.6	2/22/2017	Hong Kong	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Pending	15/440,269	2/23/2017	United States	Utility: Continuation	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Pending	15/442,110	2/24/2017	United States	Utility: Continuation	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Pending	2959992	3/2/2017	Canada	Utility: Foreign	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Pending	MX/a/2017/0028 14	3/2/2017	Mexico	Utility: Foreign	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Pending	2017-512696	3/3/2017	Japan	Utility: Foreign	
Methods and Devices for Surface Treatment	Pending	62/468,905	3/8/2017	United States	Utility: Provisional	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	2960859	3/9/2017	Canada	Utility: Foreign	
METHODS AND DEVICES FOR SMALL VOLUME LIQUID CONTAINMENT	Pending	15/456,066	3/10/2017	United States	Utility: Continuation	
DIAGNOSTIC METHODS AND COMPOSITIONS	Pending	2961209	3/13/2017	Canada	Utility: Foreign	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	15/458,528	3/14/2017	United States	Utility: Continuation	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
Hybrid Multi-Step Nucleic Acid Amplification	Pending	201717008799	3/14/2017	India	Utility: Foreign	
Methods and Devices for Surface Treatment	Pending	62/471,918	3/15/2017	United States	Utility: Provisional	
DIAGNOSTIC METHODS AND COMPOSITIONS	Pending	2017-514803	3/16/2017	Japan	Utility: Foreign	
DIAGNOSTIC METHODS AND COMPOSITIONS	Pending	MX/a/2017/0034 75	3/16/2017	Mexico	Utility: Foreign	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	BR112017005392 -6	3/16/2017	Brazil	Utility: Foreign	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	2017-514802	3/16/2017	Japan	Utility: Foreign	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	MX/a/2017/0034 73	3/16/2017	Mexico	Utility: Foreign	
Systems and methods for multi-purpose analysis	Pending	15/461,081	3/16/2017	United States	Utility: Continuation	
METHODS AND APPARATUS FOR OBTAINING UNIFORM AND STABLE EXCITATION IN CYTOMETRY NETWORK CONNECTIVITY METHODS AND SYSTEMS	Pending	62/473,249	3/17/2017	United States	Utility: Provisional	
METHODS AND SYSTEMS FOR OBTAINING CLINICAL SAMPLES	Pending	2017202096	3/29/2017	Australia	Utility: Divisional	
DIAGNOSTIC METHODS AND COMPOSITIONS	Pending	15/480,259	4/5/2017	United States	Utility: Continuation -in-Part	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	15842844.1	4/6/2017	European Patent Office	Utility: Foreign	
METHODS AND COMPOSITIONS FOR DETECTION OF VIRAL INFECTIONS	Pending	15841130.6	4/6/2017	European Patent Office	Utility: Foreign	
METHODS AND COMPOSITIONS FOR DETECTION OF VIRAL INFECTIONS	Pending	62/484,230	4/11/2017	United States	Utility: Provisional	
METHODS AND COMPOSITIONS FOR DETECTION OF VIRAL INFECTIONS	Pending	62/484,389	4/11/2017	United States	Utility: Provisional	
METHODS AND COMPOSITIONS FOR DETECTION OF ZIKA VIRAL INFECTIONS	Pending	62/484,240	4/11/2017	United States	Utility: Provisional	



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METHODS AND COMPOSITIONS FOR DETECTION OF VIRAL INFECTIONS	Pending	62/484,853	4/12/2017	United States	Utility: Provisional	
METHODS AND COMPOSITIONS FOR DETECTION OF ZIKA VIRAL INFECTIONS	Pending	62/484,716	4/12/2017	United States	Utility: Provisional	
METHODS AND COMPOSITIONS FOR IMPROVED HERPES SIMPLEX VIRUS TYPE 2 ASSAY	Pending	62/487,381	4/19/2017	United States	Utility: Provisional	
Methods and Devices for Real-Time Diagnostic Testing (RDT) for Ebola and other Infectious Diseases	Pending	201717014308	4/21/2017	India	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending	2017-85342	4/24/2017	Japan	Utility: Divisional	
FLUID HANDLING APPARATUS AND CONFIGURATIONS	Pending	15/496,959	4/25/2017	United States	Utility: Continuation	
Methods and Devices for Real-Time Diagnostic Testing (RDT) for Ebola and other Infectious Diseases	Pending	15849038.3	4/26/2017	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR ANALYTE TESTING AND LABORATORY OVERSIGHT	Pending	15/584,374	5/2/2017	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	15/584,974	5/2/2017	United States	Utility: Continuation	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND STABILIZATION	Pending	PCT/US17/31411	5/5/2017	WIPO	Utility: PCT	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Pending	17104653.1	5/9/2017	Hong Kong	Utility: Non-Provisional	
METHODS AND SYSTEMS FOR HYBRID OVERSIGHT OF SAMPLE COLLECTION	Pending	15/592,935	5/11/2017	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Pending	15/595,489	5/15/2017	United States	Utility: Continuation	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	17104923.5	5/16/2017	Hong Kong	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Pending	17104916.4	5/16/2017	Hong Kong	Utility: Foreign	
METHODS AND COMPOSITIONS FOR SUPERPARAMAGNETIC PARTICLES FOR NUCLEIC ACID EXTRACTION	Pending	62/513,999	6/1/2017	United States	Utility: Provisional	

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SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Pending	17105790.2	6/12/2017	Hong Kong	Utility: Foreign	
Spectral analysis methods based on background subtraction and curvature calculation used in the detection or quantification of hemolysis and icterus in blood-derived clinical samples	Pending	62/519,018	6/13/2017	United States	Utility: Provisional	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	17105896.5	6/14/2017	Hong Kong	Utility: Foreign	
Nucleic Acid Amplification	Pending	17105960.6	6/15/2017	Hong Kong	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Pending	17177143.9	6/21/2017	European Patent Office	Utility: Divisional	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Pending	MX/a/2017/008763	6/29/2017	Mexico	Utility: Divisional	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	17106611.7	7/3/2017	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	17106661.6	7/3/2017	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	17106706.3	7/4/2017	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	17106712.5	7/4/2017	Hong Kong	Utility: Foreign	
Nucleic Acid Amplification	Pending	15/642,746	7/6/2017	United States	Utility: Continuation	
METHODS AND COMPOSITIONS FOR IMPROVED HERPES SIMPLEX VIRUS TYPE 2 ASSAY	Pending	62/531,796	7/12/2017	United States	Utility: Provisional	
METHODS AND APPARATUS FOR LABORATORY TEST ORDERING	Pending	62/533,654	7/17/2017	United States	Utility: Provisional	
METHODS AND APPARATUS FOR PROCESSING SAMPLES	Pending	62/533,659	7/17/2017	United States	Utility: Provisional	
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Pending	10-2017-7020172	7/19/2017	Republic of Korea	Utility: Divisional	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Pending	MX/a/2017/009475	7/20/2017	Mexico	Utility: Divisional	

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POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending	10-2017-7020579	7/21/2017	Republic of Korea	Utility: Divisional	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Pending		7/24/2017	Israel	Utility: Divisional	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Pending	2017-142882	7/24/2017	Japan	Utility: Divisional	
RAPID MEASUREMENT OF TOTAL VITAMIN D IN BLOOD	Pending	15/658,920	7/25/2017	United States	Utility: Continuation	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Pending	201580058648.7	4/27/2017	China	Utility: Foreign	
Hybrid Multi-Step Nucleic Acid Amplification	Pending	201580061362.4	5/11/2017	China	Utility: Foreign	
DIAGNOSTIC METHODS AND COMPOSITIONS	Pending	201580062485.X	5/17/2017	China	Utility: Foreign	
Methods and Devices for Real-Time Diagnostic Testing (RDT) for Ebola and other Infectious Diseases	Pending	201580066627.X	6/7/2017	China	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	201280057640.5	5/23/2014	China	Utility: Foreign	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	201280057978.0	5/26/2014	China	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	201380048272.2	3/17/2015	China	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	201380048275.6	3/17/2015	China	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	201380048316.1	3/17/2015	China	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	201380049210.3	3/20/2015	China	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	201380057580.1	5/4/2015	China	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	201380058518.4	5/8/2015	China	Utility: Foreign	

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DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Published	201380067536.9	6/23/2015	China	Utility: Foreign	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Published	201380072120.6	8/3/2015	China	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	6748733	3/24/2006	European Patent Office	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	9452/DELNP/07	3/24/2006	India	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	10102788	3/24/2006	Hong Kong	Utility: Foreign	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Published	2233/DELNP/09	10/10/2007	India	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Published	09 723974.3	3/26/2009	European Patent Office	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Published	6605/CHENP/10	3/26/2009	India	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	12 737013.8	1/20/2012	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	227579	1/20/2012	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	6402/DELNP/2013	1/20/2012	India	Utility: Foreign	
Systems and Methods for Sample Use Maximization	Published	20120100204	1/20/2012	Argentina	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	13/647,325	10/8/2012	United States	Utility: Continuation	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Published	13/915,362	6/11/2013	United States	Utility: Continuation	
COMPACT CENTRIFUGE WITH THERMALLY CONDUCTIVE AND INSULATING MATERIALS	Published	13/945,202	7/18/2013	United States	Utility: Non-Provisional	
Image Analysis and Measurement of Biological Samples	Published	102126668	7/25/2013	Taiwan	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Published	14/011,730	8/27/2013	United States	Utility: Continuation	

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Systems, Devices, and Methods For Bodily Fluid Sample Collection	Published	14/020,435	9/6/2013	United States	Utility: Non-Provisional	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	14/019,946	9/6/2013	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Published	14/035,762	9/24/2013	United States	Utility: Non-Provisional	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Published	14/059,195	10/21/2013	United States	Utility: Non-Provisional	
Systems and methods for improving medical treatments	Published	14/080,727	11/14/2013	United States	Utility: Divisional	
Systems, Devices, and Methods for Bodily Fluid Sample Collection	Published	102144582	12/5/2013	Taiwan	Utility: Foreign	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Published	14/155,150	1/14/2014	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR FLUID AND COMPONENT HANDLING	Published	14/157,343	1/16/2014	United States	Utility: Continuation	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	14/167,964	1/29/2014	United States	Utility: Non-Provisional	
METHODS, SYSTEMS, AND DEVICES FOR REAL TIME EXECUTION AND OPTIMIZATION OF CONCURRENT TEST PROTOCOLS ON A SINGLE DEVICE	Published	14/181,486	2/14/2014	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/183,503	2/18/2014	United States	Utility: Non-Provisional	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	14/214,771	3/15/2014	United States	Utility: Non-Provisional	
Nucleic Acid Amplification	Published	14/214,854	3/15/2014	United States	Utility: Non-Provisional	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	12 838242.1	3/20/2014	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	231639	3/20/2014	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	2197/DELNP/2014	3/22/2014	India	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	2014-532098	3/24/2014	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	1401001625	3/25/2014	Thailand	Utility: Foreign	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	2014-533646	3/26/2014	Japan	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	14103531.4	4/11/2014	Hong Kong	Utility: Non-Provisional	
Methods, Devices and Systems for Secure Transport of Materials	Published	14/259,105	4/22/2014	United States	Utility: Non-Provisional	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	3282/DELNP/2014	4/23/2014	India	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	232544	5/11/2014	Israel	Utility: Foreign Divisional	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Published	201380072538.7	8/7/2015	China	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	14105512.2	6/11/2014	Hong Kong	Utility: Foreign	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Published	14 174846.7	6/27/2014	European Patent Office	Utility: Foreign Divisional	
Systems and Methods for Collecting and Transmitting Assay Results	Published	14/335,780	7/18/2014	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Published	14/341,745	7/25/2014	United States	Utility: Non-Provisional	
BODILY FLUID SAMPLE COLLECTION AND TRANSPORT	Published	14/446,080	7/29/2014	United States	Utility: Continuation	
BODILY FLUID SAMPLE COLLECTION AND TRANSPORT	Published	14/447,099	7/30/2014	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	201410451942.1	9/5/2014	China	Utility: Foreign Divisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
Systems and methods for conducting animal studies	Published	14/481,264	9/9/2014	United States	Utility: Continuation	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Published	8220/DELNP/2014	10/1/2014	India	Utility: Divisional	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	14/508,137	10/7/2014	United States	Utility: Continuation	
Methods and Systems for Network Connectivity	Published	14/511,861	10/10/2014	United States	Utility: Continuation	
METHODS AND SYSTEMS FOR A SAMPLE COLLECTION DEVICE WITH A NOVELTY EXTERIOR	Published	14/538,753	11/11/2014	United States	Utility: Non-Provisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	2014-237464	11/25/2014	Japan	Utility: Divisional	
LOW-VOLUME COAGULATION ASSAY	Published	11147/DELNP/2014	12/26/2014	India	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	11198/DELNP/2014	12/29/2014	India	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	11235/DELNP/2014	12/30/2014	India	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	11236/DELNP/2014	12/30/2014	India	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	13 820659.4	1/13/2015	European Patent Office	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	13 820681.8	1/13/2015	European Patent Office	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	13747735.2	1/13/2015	European Patent Office	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	13 820209.8	1/13/2015	European Patent Office	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Published	13 820103.3	1/13/2015	European Patent Office	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	236735	1/15/2015	Israel	Utility: Foreign	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	14/598,561	1/16/2015	United States	Utility: Non-Provisional	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	2015-523264	1/16/2015	Japan	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	14/598,625	1/16/2015	United States	Utility: Non-Provisional	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	2015-523270	1/16/2015	Japan	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	14/598,498	1/16/2015	United States	Utility: Continuation	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	2015-523269	1/16/2015	Japan	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Published	14/598,817	1/16/2015	United States	Utility: Non-Provisional	
LOW-VOLUME COAGULATION ASSAY	Published	2015-523268	1/16/2015	Japan	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	236767	1/18/2015	Israel	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Published	236768	1/18/2015	Israel	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	14/600,630	1/20/2015	United States	Utility: Non-Provisional	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	236819	1/20/2015	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	15100659.5	1/21/2015	Hong Kong	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	2015-524456	1/23/2015	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR DETECTING INFECTIOUS DISEASES	Published	14/604,194	1/23/2015	United States	Utility: Non-Provisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	15101073.1	1/30/2015	Hong Kong	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	14/627,307	2/20/2015	United States	Utility: Continuation	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	14/629,069	2/23/2015	United States	Utility: Continuation	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	14/631,776	2/25/2015	United States	Utility: Non-Provisional	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	PCT/US15/17581	2/25/2015	WIPO	Utility: PCT	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	2015-531263	3/5/2015	Japan	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	14/639,986	3/5/2015	United States	Utility: Non-Provisional	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	PCT/US15/19060	3/5/2015	WIPO	Utility: PCT	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	237665	3/10/2015	Israel	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	2015-531225	3/10/2015	Japan	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	PCT/US15/20307	3/12/2015	WIPO	Utility: PCT	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	201480021563.7	10/15/2015	China	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Published	201480021565.6	10/15/2015	China	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	201480021782.5	10/16/2015	China	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	237566	3/18/2015	Israel	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	201480027221.6	11/12/2015	China	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Published	2015-533286	3/24/2015	Japan	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	2656/DELNP/2015	3/31/2015	India	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	102015025315	3/31/2015	Singapore	Utility: Foreign Divisional	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	2876/DELNP/2015	4/7/2015	India	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	13 836969.9	4/8/2015	European Patent Office	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Published	238380	4/19/2015	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Published	13841597.1	4/20/2015	European Patent Office	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Published	2015-539694	4/22/2015	Japan	Utility: Foreign	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	2015-89977	4/27/2015	Japan	Utility: Foreign Divisional	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	2015-89978	4/27/2015	Japan	Utility: Foreign Divisional	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	201480027228.8	11/12/2015	China	Utility: Foreign	
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Published	13 848501.6	5/6/2015	European Patent Office	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Published	13 848352.4	5/6/2015	European Patent Office	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	201480030776.6	11/27/2015	China	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Published	201480034651.0	12/17/2015	China	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Published	201480052364.2	3/23/2016	China	Utility: Foreign	
REAL-TIME DETECTION OF INFLUENZA VIRUS	Published	2015-103390	5/21/2015	Japan	Utility: Foreign Divisional	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Published	4495/DELNP/2015	5/25/2015	India	Utility: Foreign	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Published	239062	5/28/2015	Israel	Utility: Foreign	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Published	13860491.3	6/3/2015	European Patent Office	Utility: Foreign	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Published	2015-546443	6/4/2015	Japan	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Published	2015-545937	6/9/2015	Japan	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	PCT/US15/35112	6/10/2015	WIPO	Utility: PCT	
Devices and Methods for use with a Sample Container	Published	PCT/US15/35893	6/15/2015	WIPO	Utility: PCT	
Methods and Systems for Obtaining Clinical Samples	Published	201480060451.2	5/4/2016	China	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Published	201480060454.6	5/4/2016	China	Utility: Foreign	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Published	13863036.3	6/24/2015	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/789,920	7/1/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/789,930	7/1/2015	United States	Utility: Continuation	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Published	14/789,904	7/1/2015	United States	Utility: Continuation	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Published	2015-134888	7/6/2015	Japan	Utility: Foreign Divisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
CENTRIFUGE CONFIGURATIONS	Published	14/793,625	7/7/2015	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	15106861.6	7/16/2015	Hong Kong	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	15106879.6	7/16/2015	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS for DETECTING INFECTIOUS DISEASES	Published	201480060675.3	5/5/2016	China	Utility: Foreign	
MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY	Published	14/816,426	8/3/2015	United States	Utility: Continuation	
METHODS AND SYSTEMS FOR A SAMPLE COLLECTION DEVICE WITH A NOVELTY EXTERIOR	Published	201480072687.8	7/8/2016	China	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	240538	8/12/2015	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	240537	8/12/2015	Israel	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Published	240568	8/13/2015	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/825,981	8/13/2015	United States	Utility: Continuation	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	2015-558204	8/17/2015	Japan	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Published	2015-558168	8/17/2015	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	2015-558213	8/17/2015	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/829,572	8/18/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	14/831,838	8/20/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/839,749	8/28/2015	United States	Utility: Continuation	
Systems and Methods for Collecting and Transmitting Assay Results	Published	7921/DELNP/2015	9/2/2015	India	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	241072	9/2/2015	Israel	Utility: Foreign	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Published	241073	9/2/2015	Israel	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	14/845,740	9/4/2015	United States	Utility: Continuation	
THERMOSTABLE BLUNT-END LIGASE AND METHODS OF USE	Published	14/846,285	9/4/2015	United States	Utility: Continuation	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Published	PCT/US15/48533	9/4/2015	WIPO	Utility: PCT	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	14751601.7	9/7/2015	European Patent Office	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	8086/DELNP/2015	9/7/2015	India	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	241270	9/7/2015	Israel	Utility: Foreign	
Systems and Methods for Collecting and Transmitting Assay Results	Published	14751655.3	9/7/2015	European Patent Office	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	241272	9/7/2015	Israel	Utility: Foreign	
Nucleic Acid Amplification	Published	241269	9/7/2015	Israel	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Published	241274	9/7/2015	Israel	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Published	241273	9/7/2015	Israel	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	14/848,032	9/8/2015	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	14/848,084	9/8/2015	United States	Utility: Continuation	
NUCLEIC ACID AMPLIFICATION	Published	14/848,220	9/8/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/848,775	9/9/2015	United States	Utility: Continuation	

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NUCLEIC ACID AMPLIFICATION	Published	14/850,697	9/10/2015	United States	Utility: Continuation	
NUCLEIC ACID AMPLIFICATION	Published	241426	9/10/2015	Israel	Utility: Foreign	
Nucleic Acid Amplification	Published	14/850,608	9/10/2015	United States	Utility: Continuation	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	2016-503463	9/11/2015	Japan	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	2016-503326	9/11/2015	Japan	Utility: Foreign	
Nucleic Acid Amplification	Published	2016-503313	9/11/2015	Japan	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Published	2016-502563	9/11/2015	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14751559.7	9/14/2015	European Patent Office	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	2016-501087	9/14/2015	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/855,303	9/15/2015	United States	Utility: Continuation	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	14/854,382	9/15/2015	United States	Utility: Continuation	
BIOLOGICAL SAMPLE PROCESSING	Published	14/855,249	9/15/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/857,224	9/17/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/857,407	9/17/2015	United States	Utility: Continuation	
DIAGNOSTIC METHODS AND COMPOSITIONS	Published	PCT/US15/50811	9/17/2015	WIPO	Utility: PCT	
Hybrid Multi-Step Nucleic Acid Amplification	Published	PCT/US15/50822	9/17/2015	WIPO	Utility: PCT	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/860,048	9/21/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/860,149	9/21/2015	United States	Utility: Continuation	



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METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	241803	9/21/2015	Israel	Utility: Foreign	
BIOLOGICAL SAMPLE PROCESSING	Published	241804	9/21/2015	Israel	Utility: Foreign	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	8844/DELNP/2015	9/25/2015	India	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	2016-505575	9/25/2015	Japan	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Published	14/865,603	9/25/2015	United States	Utility: Continuation	
CALIBRATION OF FLUIDIC DEVICES	Published	14/867,271	9/28/2015	United States	Utility: Continuation	
Systems and Methods of Sample Processing and Fluid Control in a Fluidic System	Published	14/868,208	9/28/2015	United States	Utility: Continuation	
NETWORK CONNECTIVITY METHODS AND SYSTEMS	Published	14760282.5	9/30/2015	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/872,995	10/1/2015	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	14/872,718	10/1/2015	United States	Utility: Continuation	
NUCLEIC ACID AMPLIFICATION	Published	14762742.6	10/5/2015	European Patent Office	Utility: Foreign	
Methods and Devices for Real-Time Diagnostic Testing (RDT) for Ebola and other Infectious Diseases	Published	PCT/US2015/054618	10/8/2015	WIPO	Utility: PCT	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	15109850.3	10/8/2015	Hong Kong	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	14763454.7	10/12/2015	European Patent Office	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	14768967.3	10/12/2015	European Patent Office	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	14764049.4	10/12/2015	European Patent Office	Utility: Foreign	
NUCLEIC ACID AMPLIFICATION	Published	14762846.5	10/12/2015	European Patent Office	Utility: Foreign	

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Nucleic Acid Amplification	Published	14/880,521	10/12/2015	United States	Utility: Continuation	
Nucleic Acid Amplification	Published	14763758.1	10/12/2015	European Patent Office	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Published	14764499.1	10/12/2015	European Patent Office	Utility: Foreign	
Nucleic Acid Amplification	Published	201480073710.5	7/20/2016	China	Utility: Foreign	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Published	201510236747.1	5/11/2015	China	Utility: Foreign Divisional	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Published	242110	10/15/2015	Israel	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	201580015162.5	9/20/2016	China	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	14775078	10/19/2015	European Patent Office	Utility: Foreign	
BIOLOGICAL SAMPLE PROCESSING	Published	14773663.1	10/19/2015	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/918,090	10/20/2015	United States	Utility: Continuation	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Published	2016-510745	10/21/2015	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR FLUID AND COMPONENT HANDLING	Published	14/928,087	10/30/2015	United States	Utility: Continuation	
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Published	14787543.9	11/2/2015	European Patent Office	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	15110933.2	11/5/2015	Hong Kong	Utility: Foreign	
METHODS, DEVICES, AND SYSTEMS FOR MIXING FLUIDS	Published	PCT/US15/59421	11/6/2015	WIPO	Utility: PCT	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	201580015419.7	9/21/2016	China	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	201580020727.9	10/20/2016	China	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	201580021952.4	11/1/2016	China	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	201580026120.1	11/11/2016	China	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	15111429.1	11/19/2015	Hong Kong	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	15111431.7	11/19/2015	Hong Kong	Utility: Foreign	
METHODS AND SYSTEMS FOR HYBRID OVERSIGHT OF SAMPLE COLLECTION	Published	14/952,610	11/25/2015	United States	Utility: Non-Provisional	
METHODS AND SYSTEMS FOR HYBRID OVERSIGHT OF SAMPLE COLLECTION	Published	PCT/US15/62741	11/25/2015	WIPO	Utility: PCT	
LOW-VOLUME COAGULATION ASSAY	Published	15111614.6	11/25/2015	Hong Kong	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	14/963,030	12/8/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/965,665	12/10/2015	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	14/965,725	12/10/2015	United States	Utility: Continuation	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Published	201610423953.8	6/15/2016	China	Utility: Divisional	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	15112688.5	12/24/2015	Hong Kong	Utility: Foreign	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	16100170.4	1/8/2016	Hong Kong	Utility: Foreign	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	16100172.2	1/8/2016	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	10201600463Y	1/21/2016	Singapore	Utility: Divisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Published	2016-530090	1/22/2016	Japan	Utility: Foreign	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Published	243760	1/24/2016	Israel	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	15/005,897	1/25/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	15/006,349	1/26/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Published	16101278.3	2/2/2016	Hong Kong	Utility: Foreign	
SYSTEMS AND METHODS for DETECTING INFECTIOUS DISEASES	Published	15/041,421	2/11/2016	United States	Utility: Non-Provisional	
Methods and Systems for Obtaining Clinical Samples	Published	15/041,744	2/11/2016	United States	Utility: Continuation	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Published	15/041,488	2/11/2016	United States	Utility: Non-Provisional	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Published	15/042,909	2/12/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR A DISTRIBUTED CLINICAL LABORATORY	Published	14829161	2/16/2016	European Patent Office	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Published	201617005938	2/19/2016	India	Utility: Foreign	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Published	10201601353P	2/23/2016	Singapore	Utility: Divisional	
METHODS AND SYSTEMS FOR OBTAINING CLINICAL SAMPLES	Published	PCT/US16/19160	2/23/2016	WIPO	Utility: PCT	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Published	16102002.4	2/23/2016	Hong Kong	Utility: Foreign	
APPOINTMENT SCHEDULING AND CHECK IN	Published	15/054,047	2/25/2016	United States	Utility: Continuation	
Methods, Devices, and Systems Having Multiple Passwords	Published	15/054,966	2/26/2016	United States	Utility: Continuation	
Detection and Quantification of Analytes in Bodily Fluids	Published	15/054,510	2/26/2016	United States	Utility: Continuation	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Published	16102367.3	3/1/2016	Hong Kong	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Published	244394	3/2/2016	Israel	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Published	244395	3/2/2016	Israel	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Published	2016-540448	3/4/2016	Japan	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Published	2016-540446	3/4/2016	Japan	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Published	244469	3/7/2016	Israel	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Published	2016-540917	3/7/2016	Japan	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Published	201610430085.6	6/16/2016	China	Utility: Divisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	2016101397987	3/11/2016	China	Utility: Non-Provisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	2016101412737	3/11/2016	China	Utility: Divisional	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	15/069,843	3/14/2016	United States	Utility: Continuation	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Published	14 841868.4	3/14/2016	European Patent Office	Utility: Foreign	
DEVICES, SYSTEMS, METHODS, AND KITS FOR RECEIVING A SWAB	Published	14 841645.6	3/14/2016	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	10201602141Q	3/18/2016	Singapore	Utility: Divisional	
REDUCING OPTICAL INTERFERENCE IN A FLUIDIC DEVICE	Published	244688	3/20/2016	Israel	Utility: Divisional	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	2016101417270	3/11/2016	China	Utility: Divisional	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Published	16103524.1	3/24/2016	Hong Kong	Utility: Foreign	

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<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
Methods and Systems for Obtaining Clinical Samples	Published	14843011.9	3/30/2016	European Patent Office	Utility: Foreign	
DIAGNOSTIC METHODS AND COMPOSITIONS	Published	15/087,840	3/31/2016	United States	Utility: Continuation	
Methods, Devices, Systems, and Kits for Automated Blood Collection by Fingertick	Published	15/087,109	3/31/2016	United States	Utility: Non-Provisional	
Methods, Devices, Systems, and Kits for Automated Blood Collection by Fingertick	Published	PCT/US16/25212	3/31/2016	WIPO	Utility: PCT	
Systems, Devices, and Methods for Bodily Fluid Sample Transport	Published	16103780	4/1/2016	Hong Kong	Utility: Foreign	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Published	201617011739	4/2/2016	India	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Published	15/092,279	4/6/2016	United States	Utility: Continuation	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	15/092,499	4/6/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR ORDERING LABORATORY TESTS AND PROVIDING RESULTS THEREOF	Published	15/098,159	4/13/2016	United States	Utility: Continuation	
Rapid Measurement of Formed Blood Component Sedimentation Rate from Small Sample Volumes	Published	15/132,906	4/19/2016	United States	Utility: Continuation	
Rapid, Low-Sample-Volume Cholesterol and Triglyceride Assays	Published	16104594.4	4/21/2016	Hong Kong	Utility: Foreign	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	15/140,902	4/28/2016	United States	Utility: Divisional	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	15/140,993	4/28/2016	United States	Utility: Continuation	
METHODS AND SYSTEMS FOR A SAMPLE COLLECTION DEVICE WITH A NOVELTY EXTERIOR	Published	15/143,908	5/2/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	2016106500679	8/10/2016	China	Utility: Divisional	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	2016106517491	8/10/2016	China	Utility: Divisional	

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SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	2016106518013	8/10/2016	China	Utility: Divisional	
Methods and Systems for Obtaining Clinical Samples	Published	14853747.5	5/9/2016	European Patent Office	Utility: Foreign	
Nucleic Acid Amplification	Published	15/152,997	5/12/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR ORDERING LABORATORY TESTS AND PROVIDING RESULTS THEREOF	Published	14856077.4	5/16/2016	European Patent Office	Utility: Foreign	
LOW-VOLUME COAGULATION ASSAY	Published	10201603916U	5/16/2016	Singapore	Utility: Divisional	
Nucleic Acid Amplification	Published	245687	5/17/2016	Israel	Utility: Foreign	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Published	15/159,399	5/19/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	15/159,501	5/19/2016	United States	Utility: Continuation	
DRUG MONITORING AND REGULATION SYSTEMS AND METHODS	Published	15/159,568	5/19/2016	United States	Utility: Continuation	
METHODS, SYSTEMS, AND DEVICES FOR REAL TIME EXECUTION AND OPTIMIZATION OF CONCURRENT TEST PROTOCOLS ON A SINGLE DEVICE	Published	15/159,593	5/19/2016	United States	Utility: Continuation	
INFORMATION MANAGEMENT SYSTEMS AND METHODS USING A BIOLOGICAL SIGNATURE	Published	15/159,620	5/19/2016	United States	Utility: Continuation	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE TRANSPORT	Published	15/160,196	5/20/2016	United States	Utility: Continuation	
Nucleic Acid Amplification	Published	2016-533175	5/20/2016	Japan	Utility: Foreign	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	15/160,491	5/20/2016	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	15/160,578	5/20/2016	United States	Utility: Continuation	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	16105856.4	5/23/2016	Hong Kong	Utility: Foreign	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	15/162,122	5/23/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	15/161,533	5/23/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	15/161,547	5/23/2016	United States	Utility: Continuation	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	16105862.6	5/23/2016	Hong Kong	Utility: Foreign	
Methods and Devices for Real-Time Diagnostic Testing (RDT) for Ebola and other Infectious Diseases	Published	15/162,216	5/23/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	2016-106082	5/27/2016	Japan	Utility: Divisional	
LOW-VOLUME COAGULATION ASSAY	Published	15/166,699	5/27/2016	United States	Utility: Divisional	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	16106200.5	5/31/2016	Hong Kong	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	16106198.9	5/31/2016	Hong Kong	Utility: Foreign	
Nucleic Acid Amplification	Published	201617018755	5/31/2016	India	Utility: Foreign	
METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES	Published	246042	6/2/2016	Israel	Utility: Divisional	
Systems and Methods for Collecting and Transmitting Assay Results	Published	16106499.5	6/7/2016	Hong Kong	Utility: Foreign	
METHODS AND SYSTEMS FOR A SAMPLE COLLECTION DEVICE WITH A NOVELTY EXTERIOR	Published	14859931.9	6/9/2016	European Patent Office	Utility: Foreign	
METHODS FOR DETECTING AND MEASURING AGGREGATION	Published	15/179,769	6/10/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	2016106519603	8/10/2016	China	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	15/183,600	6/15/2016	United States	Utility: Continuation	
Nucleic Acid Amplification	Published	14 864826.4	6/15/2016	European Patent Office	Utility: Foreign	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	15/184,923	6/16/2016	United States	Utility: Divisional	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	2016-119643	6/16/2016	Japan	Utility: Divisional	
DEVICES, SYSTEMS AND METHODS FOR SAMPLE PREPARATION	Published	16107548.4	6/28/2016	Hong Kong	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	10201605479Q	7/4/2016	Singapore	Utility: Divisional	
LOW-VOLUME COAGULATION ASSAY	Published	201380048398.X	3/17/2015	China	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	2016-139081	7/14/2016	Japan	Utility: Divisional	
SYSTEMS AND METHODS FOR RESPONSE CALIBRATION	Published	201380060909.X	5/21/2015	China	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	2016-547876	7/21/2016	Japan	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	2016-547875	7/21/2016	Japan	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION, TRANSPORT, AND HANDLING	Published	15/216,658	7/21/2016	United States	Utility: Non-Provisional	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION, TRANSPORT, AND HANDLING	Published	PCT/US16/43435	7/21/2016	WIPO	Utility: PCT	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	15/217,207	7/22/2016	United States	Utility: Divisional	
MODULAR POINT-OF-CARE DEVICES, SYSTEMS, AND USES THEREOF	Published	15/217,360	7/22/2016	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	10201606120X	7/25/2016	Singapore	Utility: Divisional	
TRANSFER VESSEL AND METHODS FOR REDUCING SAMPLE LOSS	Published	PCT/US16/45199	8/2/2016	WIPO	Utility: PCT	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
METHODS, DEVICES, AND SYSTEMS FOR SECURE TRANSPORT OF MATERIALS	Published	16109546.2	8/10/2016	Hong Kong	Utility: Foreign	
ASSISTED MEDICAL AND ASSOCIATED LIFESTYLE DECISION MAKING	Published	201380067527.X	6/23/2015	China	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	201480027545.X	11/12/2015	China	Utility: Foreign	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Published	201480027584.X	11/12/2015	China	Utility: Foreign	
Nucleic Acid Amplification	Published	201480027922.X	11/13/2015	China	Utility: Foreign	
Methods and Systems for Obtaining Clinical Samples	Published	201480068008.X	6/13/2016	China	Utility: Foreign	
RAPID MEASUREMENT OF FORMED BLOOD COMPONENT SEDIMENTATION RATE FROM SMALL SAMPLE VOLUMES	Published	15 740716.4	8/16/2016	European Patent Office	Utility: Foreign	
HIGH SPEED, COMPACT CENTRIFUGE FOR USE WITH SMALL SAMPLE VOLUMES	Published	15 740419.5	8/16/2016	European Patent Office	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	15/242,171	8/19/2016	United States	Utility: Continuation	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	15/244,990	8/23/2016	United States	Utility: Continuation	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	2016-553840	8/24/2016	Japan	Utility: Foreign	
INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM	Published	15/246,401	8/24/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR MULTI-ANALYSIS	Published	16110168.7	8/25/2016	Hong Kong	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	PCT/US16/49133	8/26/2016	WIPO	Utility: PCT	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	15/250,530	8/29/2016	United States	Utility: Non-Provisional	
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF	Published	201618029659	8/31/2016	India	Utility: Divisional	



<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	2016-555595	9/2/2016	Japan	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR SAMPLE INTEGRITY VERIFICATION	Published	15 754417.2	9/5/2016	European Patent Office	Utility: Foreign	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	2016-556284	9/8/2016	Japan	Utility: Foreign	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	15/261,802	9/9/2016	United States	Utility: Non-Provisional	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	PCT/US16/51158	9/9/2016	WIPO	Utility: PCT	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	15/278,333	9/28/2016	United States	Utility: Divisional	
METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION	Published	15757840.2	10/4/2016	European Patent Office	Utility: Foreign	
BODILY FLUID SAMPLE COLLECTION AND TRANSPORT	Published	PCT/US16/56161	10/7/2016	WIPO	Utility: PCT	
SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION	Published	15761006.4	10/11/2016	European Patent Office	Utility: Foreign	
BODILY FLUID SAMPLE COLLECTION AND TRANSPORT	Published	15/290,248	10/11/2016	United States	Utility: Non-Provisional	
FEMTOWATT NON-VACUUM TUBE DETECTOR ASSEMBLY	Published	15/299,077	10/20/2016	United States	Utility: Continuation	
SYSTEMS AND METHODS FOR SAMPLE USE MAXIMIZATION	Published	201610652305X	8/10/2016	China	Utility: Divisional	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	15/340,637	11/1/2016	United States	Utility: Divisional	
METHODS, DEVICES, AND SYSTEMS FOR MIXING FLUIDS	Published	15/342,450	11/3/2016	United States	Utility: Continuation	
SYSTEMS and METHODS for DETECTING INFECTIOUS DISEASES	Published	15/356,972	11/21/2016	United States	Utility: Divisional	
RAPID, LOW-SAMPLE-VOLUME CHOLESTEROL AND TRIGLYCERIDE ASSAYS	Published	15/364,762	11/30/2016	United States	Utility: Continuation	
IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES	Published	10201610783R	12/22/2016	Singapore	Utility: Divisional	

<u>Title</u>	<u>Status</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Country</u>	<u>Type</u>	<u>Patent Number</u>
MULTI-PIECE FLUID TRANSFER TIP	Published	15/388,095	12/22/2016	United States	Utility: Non-Provisional	
MULTI-PIECE FLUID TRANSFER TIP	Published	PCT/US16/68237	12/22/2016	WIPO	Utility: PCT	
METHODS, DEVICES, AND SYSTEMS FOR SAMPLE ANALYSIS	Published	15807539	1/11/2017	European Patent Office	Utility: Foreign	
SYSTEMS AND METHODS OF FLUIDIC SAMPLE PROCESSING	Published	15/403,553	1/11/2017	United States	Utility: Continuation	
MODULAR POINT-OF-CARE DEVICES, AND USES THEREOF	Published	17155280.5	2/8/2017	European Patent Office	Utility: Divisional	
PATHOGEN AND ANTIMICROBIAL RESISTANCE TESTING	Published	15837388.6	3/30/2017	European Patent Office	Utility: Foreign	

EXHIBIT 3

(FILED UNDER SEAL)

EXHIBIT 4

(FILED UNDER SEAL)

EXHIBIT 5



1701 Page Mill Road
Palo Alto, CA 94304

P 650.838.9292
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theranos.com

CONFIDENTIAL COMMERCIAL INFORMATION
EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

August 26, 2015

To Whom It May Concern:

Pursuant to your request for our specific configurations of the Theranos Capillary Tubes and Nanotainer Tubes used with the LDTs run in the Theranos clinical laboratory, please see the attached.

Theranos Internal Only

List of tests using
nanotainers,
Shirley gave 10:15 AM
8/26

Ian - has the tests for
high corp. lab.

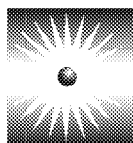
CONFIDENTIAL COMMERCIAL INFORMATION
EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

CONFIDENTIAL COMMERCIAL INFORMATION
EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

LIST OF LDTs in Theranos High Complexity CLIA Certified Lab as of 8.26.2015

Assay Name	Assay Device Type	Container	Analyzer	Anticoagulant
alanine amino (alt) (sgpt)	LDT	NT	ADVIA	Heparin
albumin, serum	LDT	NT	ADVIA	Heparin
alkaline phosphatase	LDT	NT	ADVIA	Heparin
automated leukocyte count, BD FORTESSA	LDT	NT	BDFLOW	EDTA
automated platelet count	LDT	NT	DREW	EDTA
bilirubin, total	LDT	NT	ADVIA	Heparin
calcium	LDT	NT	ADVIA	Heparin
carbon dioxide, blood	LDT	NT	ADVIA	Heparin
chloride, blood	LDT	NT	ADVIA	Heparin
cholesterol, bld/serum	LDT	NT	ADVIA	Heparin
c-reactive protein	LDT	NT	ADVIA	EDTA
creatinine	LDT	NT	ADVIA	Heparin
Fasting Glucose in Serum or Plasma	LDT	NT	ADVIA	Heparin
ferritin	LDT	NT	ADVIA	EDTA
hematocrit, by centrifugation	LDT	NT	DREW	EDTA
hemoglobin	LDT	NT	DREW	EDTA
Total Iron	LDT	NT	ADVIA	Heparin
Total Iron binding capacity	LDT	NT	ADVIA	Heparin
lipase	LDT	NT	ADVIA	Heparin
lipoprotein (HDL)	LDT	NT	ADVIA	Heparin
transferase (ast) (sgot)	LDT	NT	ADVIA	Heparin
lipoprotein, blood (LDL)	LDT	NT	ADVIA	Heparin
magnesium	LDT	NT	ADVIA	Heparin
triglycerides, Serum or Plasma	LDT	NT	ADVIA	Heparin
mean cell volume	LDT	NT	DREW	EDTA
urea nitrogen	LDT	NT	ADVIA	Heparin
uric acid, blood	LDT	NT	ADVIA	Heparin
phosphorus	LDT	NT	ADVIA	Heparin
potassium, serum	LDT	NT	ADVIA	Heparin
protein total, serum	LDT	NT	ADVIA	Heparin
rbc sed rate, automated	LDT	NT	IMAGING	EDTA
sodium, serum	LDT	NT	ADVIA	Heparin
c-reactive protein, hs	LDT	NT	ADVIA	EDTA

EXHIBIT 6



OraSure Technologies, Inc.

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Customer Letter

Dear Customer,

Thank you for deciding to use the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The sale, distribution, and use of this product is restricted as described in the product insert. By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the following restrictions on the sale, distribution, and use of the device:

1. Sale of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is restricted to clinical laboratories
 - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met¹⁻³; and
 - where there is assurance that operators will receive and use the instructional materials.
2. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is approved for use only by an agent of a clinical laboratory.
3. Test subjects must receive the "Subject Information" pamphlet and pre-test counseling prior to specimen collection, and appropriate counseling when test results are provided.
4. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is not approved for use to screen blood or tissue donors.

The package insert for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test contains warnings and precautions, restrictions on the sale, distribution, and use of the device, and information about how the device works, how to use the device, interpretation of results, and limitations of the procedure. The "Subject Information" pamphlet provides subjects with information about the limitations of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and the meaning of a preliminary positive or negative test result with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, as well as general information about HIV and AIDS. You should review all of these materials yourself.

If you have any questions, please call us toll-free at 1-800-ORASURE (1-800-672-7873) or 1-800-869-3538 and ask for customer service.

Sincerely,

OraSure Technologies' Customer Service

References

1. CLSI Document GP2-A4, Clinical Laboratory Technical Procedure Manuals
2. CLSI Document GP27-A, Using Proficiency Testing (PT) to Improve the Clinical Laboratory
3. CLSI Document AST2-A, Point-of-Care In Vitro (IVD) Testing

220 East First Street, Bethlehem, PA 18015
Phone 610-882-1820 • Fax 610-882-2275
www.orasure.com



Read this package insert completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results. Before performing testing, all operators **MUST** read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.^{5,9}

COMPLEXITY: WAIVED

for Oral Fluid, Fingerstick Whole Blood and Venipuncture Whole Blood. Any modification by the laboratory to the test system or FDA approved test system instructions will result in the test no longer meeting the requirements for waived category.

COMPLEXITY: MODERATE

for Plasma.

NAME AND INTENDED USE

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood, venipuncture whole blood and plasma specimens. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

RESTRICTIONS

- **Sale of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is restricted to clinical laboratories**
 - **that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and**
 - **where there is assurance that operators will receive and use the instructional materials.**
- **The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is approved for use only by an agent of a clinical laboratory.**
- **Test subjects must receive the "Subject Information" pamphlet prior to specimen collection and appropriate information when test results are provided.**
- **The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is not approved for use to screen blood or tissue donors.**

SUMMARY AND EXPLANATION OF THE TEST

Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC) and pre-AIDS are thought to be caused by the Human Immunodeficiency Virus (HIV). The first AIDS-related virus, HIV-1 (also known as HTLV-III, LAV-1 and ARV) has been isolated from patients with AIDS and from healthy persons at high risk for AIDS.^{1,2} Genetic analysis of HIV-1 isolates has documented the existence of subtypes. To date, eight HIV-1 subtypes (A through H), designated as Group M, have been identified world-wide in addition to the highly divergent HIV-1 isolates from AIDS patients in Cameroon, designated as Group O.³ A closely related but distinct second type of pathogenic human immunodeficiency retrovirus, designated HIV-2 (formerly LAV-2), has been isolated from West African patients with AIDS. HIV-2 has been shown to share a number of conserved sequences with HIV-1, but serological cross-reactivity between HIV-1 and HIV-2 has been shown to be highly variable from sample to sample.

HIV is known to be transmitted by sexual contact, by exposure to blood (including sharing contaminated needles and syringes) or by contaminated blood products, or it may be transmitted from an infected mother to her fetus during the prenatal period. Individuals infected with HIV produce antibodies against the HIV viral proteins. Testing for the presence of antibodies to HIV in bodily fluids (e.g., blood, oral fluid, and urine) is an accurate aid in the diagnosis of HIV infection. However, the implications of seropositivity must be considered in a clinical context. For example, in neonates, the presence of antibodies to HIV is indicative of exposure to HIV, but not necessarily of HIV infection, due to the acquisition of maternal antibodies that may persist for up to eighteen months. Conversely, absence of antibody to HIV cannot be taken as absolute proof that an individual is free of HIV infection or incapable of transmitting the virus. An antibody response to a recent exposure may take several months to reach detectable levels. HIV has been isolated from asymptomatic, seronegative individuals presumably before seroconversion following exposure.

The standard laboratory HIV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EIA) and confirmation of repeatedly reactive EIAs using a Western blot test. Results are typically reported within 48 hours to 2 weeks, making these standard screening and supplemental tests inadequate to meet the need for rapid HIV diagnosis. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

Using a rapid HIV test increases the number of HIV-infected persons who may be diagnosed. The Centers for Disease Control and Prevention (CDC) estimates that nearly one third of the estimated 900,000 HIV-infected persons in the United States do not know their HIV status. As a result, they cannot benefit from early intervention with effective antiviral therapy. Rapid HIV testing addresses this

issue by providing results during the initial visit and enabling immediate counseling. Additionally, for pregnant women who do not know their HIV status at the time of delivery, rapid HIV testing permits therapy to be initiated for these mothers during labor, and to their infants post partum, substantially reducing the chance that the infants will become infected with HIV. Likewise, rapid HIV testing is instrumental in the decision to initiate treatment for health care workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 600,000 to 1,000,000 "needlestick injuries" occur each year. Critical decisions about treatment depend on the availability of accurate, rapid HIV test results.

BIOLOGICAL PRINCIPLES OF THE TEST

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid, whole blood obtained from a finger puncture or a venipuncture, and plasma. The OraQuick *ADVANCE*® rapid test is comprised of a single-use test device and a single-use vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in separate compartments of a single pouch to form the test. The OraQuick *ADVANCE*® rapid test utilizes a proprietary lateral flow immunoassay procedure. The device plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

An oral fluid specimen is collected using the flat pad on the test device, followed by the insertion of the test device into the vial of developer solution. A fingerstick whole blood, venipuncture whole blood or plasma specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

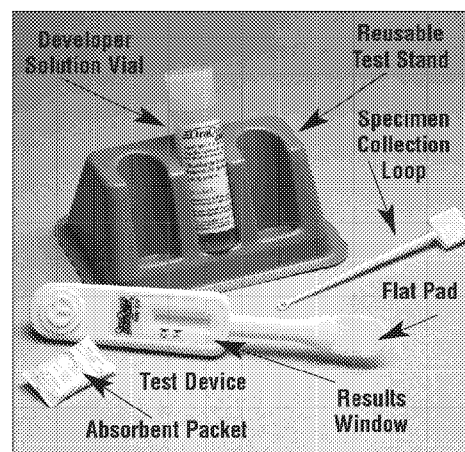
Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1 and/or HIV-2 (refer to the *Test Result and Interpretation of Test Result* section below).

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen. No precision pipeting, predilutions, or specialized instrumentation are required to perform the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

MATERIALS PROVIDED

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kits are available in the following packaging configurations:

Kit Size	100 Count	25 Count
Divided Pouches, each containing: Test Device (1) Absorbent Packet (1) Developer Solution Vial (1) (each vial contains 1 mL of a phosphate buffered saline solution containing polymers and an antimicrobial agent)	100	25
Reusable Test Stands	10	5
Specimen Collection Loops	100	25
Subject Information Pamphlets	100	25
Package Insert	1	1
Customer Letter	1	1



MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls

Package contains HIV-1 Positive Control (1 vial, black cap, 0.2 mL), HIV-2 Positive Control (1 vial, red cap, 0.2 mL) and Negative Control (1 vial, white cap, 0.2 mL), and a Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 20 to 40 minutes

Clean, disposable, absorbent workspace cover

Biohazard waste container

Additional items required for fingerstick and venipuncture whole blood collection, and plasma specimens:

Antiseptic wipe

Sterile lancet to obtain a fingerstick whole blood specimen, or materials required to obtain a venipuncture whole blood specimen

Sterile gauze pads

Latex, vinyl or nitrile disposable gloves (optional for oral fluid testing)

Centrifuge to process a plasma specimen

WARNINGS**For *in vitro* Diagnostic Use**

1. Read the package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
2. Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.^{5,9}
3. FDA has approved this kit for use with oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens only. Use of this test kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results.
4. This test should be performed at temperatures in the range of (15°- 37°C, 59°- 99°F). If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°- 37°C, 59°- 99°F) before performing testing.
5. If the test kit is stored at temperatures outside of ambient temperature (2°- 27°C, 35°- 80°F), or used outside of the operating temperature (15°- 37°C, 59°- 99°F), use the Kit Controls to ensure performance of the test.
6. Individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.

PRECAUTIONS**Safety Precautions**

1. Handle blood specimens and materials contacting blood specimens as if capable of transmitting infectious agents.
2. Do not drink, eat, or smoke in areas where specimens are being handled or testing is being performed.
3. Wear disposable gloves while handling blood specimens and performing testing of blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
4. Oral fluid is not considered potentially infectious unless it contains blood.⁹ Use of gloves for oral fluid testing is optional. Test administrators with breaks in the skin (cuts, abrasions, or dermatitis) should wear gloves when performing oral fluid testing. Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.
5. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container. Lancets and venipuncture materials should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**
6. Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant⁴. Bleach solutions should be made fresh each day.
7. For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings"^{5,9} and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis".⁸

Handling Precautions

1. Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety Precautions). **Do not reuse any of these test components.**
2. Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
3. Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
4. Avoid microbial contamination and exercise care in handling the kit components.
5. To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the fingerstick whole blood, venipuncture whole blood or plasma sample.
6. When collecting oral fluid specimens the Test Device must be inserted into the Developer Solution Vial within 30 minutes of collection. A Test Device containing an oral fluid specimen that is not inserted into the Developer Solution Vial within 10 minutes of collection should be either stored on a flat surface or returned to the Divided Pouch after the desiccant has been removed from the Divided Pouch. For a 10-30 minute delay in insertion, return the Test Device containing the oral fluid specimen to the Divided Pouch after the desiccant has been removed from the Divided Pouch. Ensure that the Divided Pouch containing the Test Device is kept in a horizontal position until the Test Device is inserted into the Developer Solution Vial.
7. Adequate lighting is required to read a test result.

STORAGE INSTRUCTIONS

Store unused OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Tests unopened at 2°-27°C (35°-80°F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°-37°C, 59°-99°F) before opening.

DIRECTIONS FOR USE

SET UP YOUR WORKSPACE

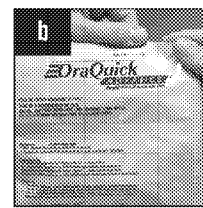
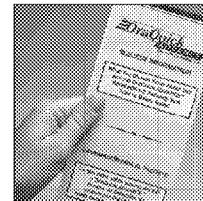
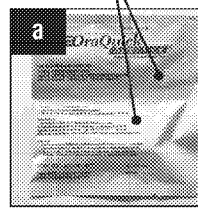
- Gather the materials you will need.
- Allow the test kit to come to operating temperature (15°-37°C; 59°-99°F) before use.
- Refer to the *External Quality Control* section in this package insert to determine when the Kit Controls should be run.
- Cover your workspace with a clean, disposable, absorbent workspace cover.
- Set an OraQuick *ADVANCE*® Reusable Test Stand ("Stand") up on your workspace cover. Use only the stand provided.
- Put on your disposable gloves as required in accordance with the *Safety Precautions* section in this package insert.

Prior to testing provide the "Subject Information" pamphlet to the person being tested.

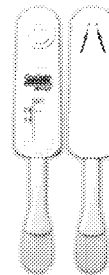
GENERAL TEST PREPARATION

1. Open the two chambers of the OraQuick *ADVANCE*® Divided Pouch ("Pouch") by tearing at the notches on the top of each side of the Pouch (see *picture a and b*). To prevent contamination, leave the Test Device ("Device") in the Pouch until you are ready to use it.
2. Remove the Developer Solution Vial ("Vial") from the Pouch. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off. Set the cap on your workspace cover.
3. Slide the Vial into the top of one of the slots in the Stand. **DO NOT** force the vial into the Stand from the front of the slot as splashing may occur. Make sure the Vial is pushed all the way to the bottom of the slot in the stand (see *picture c*).

Two Chambers



NOTE: DO NOT cover the two holes in the back of the Device with labels or other materials. Doing so may cause an invalid result.



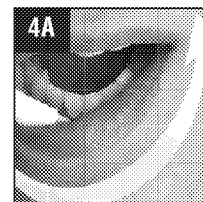
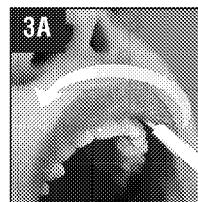
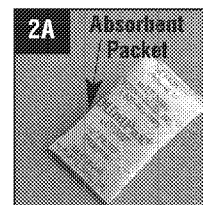
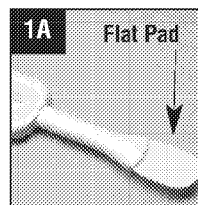
SPECIMEN COLLECTION AND TESTING PROCEDURE

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test can be used for testing oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens. Refer to the specific testing procedure below.

ORAL FLUID PROCEDURE

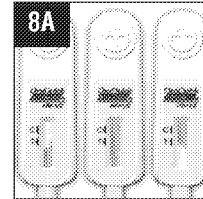
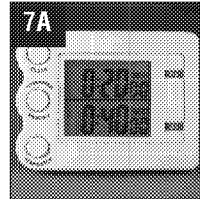
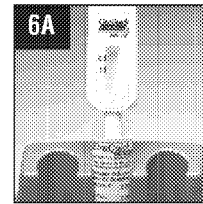
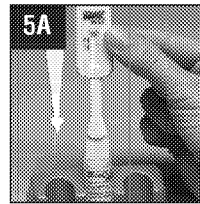
STEP 1: COLLECT

1. Ensure prior to testing that the subject has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products.
2. Have the person being tested remove the Device from its Pouch. **DO NOT** allow the person to touch the Flat Pad (see *picture 1A*). Check to make sure that an Absorbent Packet is included with the Device (see *picture 2A*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
3. Direct the person to place the Flat Pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad (see *pictures 3A and 4A*). **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. **NOTE:** Both sides of the Flat Pad may be used during this procedure.



STEP 2: TEST

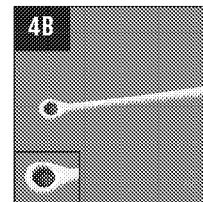
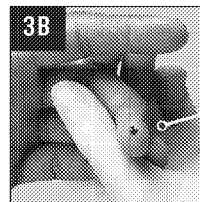
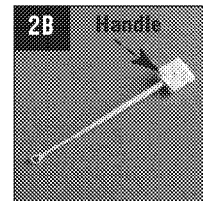
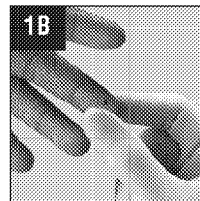
1. Insert the Flat Pad of the Device all the way into the Vial (see picture 5A). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 6A).
2. Start timing the test (see picture 7A). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 8A). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
3. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.

**FINGERSTICK WHOLE BLOOD AND VENIPUNCTURE WHOLE BLOOD PROCEDURE****STEP 1: COLLECT**

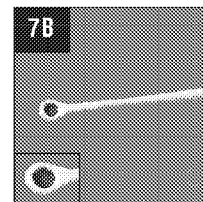
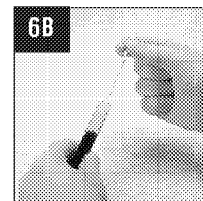
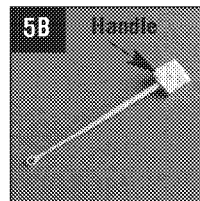
Whole blood specimens may be collected either by fingerstick (see Step 1.A) or by venipuncture (see Step 1.B).

STEP 1.A: FINGERSTICK WHOLE BLOOD

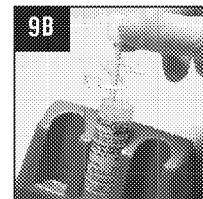
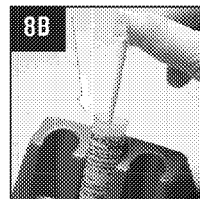
1. Using an antiseptic wipe, clean the finger of the person being tested. After cleansing the skin puncture site, allow the area to air dry, so the antiseptic action of the alcohol can take effect. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (see picture 1B). Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see picture 2B). Put the "rounded" end of the Loop on the drop of blood (see picture 3B). Make sure that the Loop is completely filled with blood (see picture 4B). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

**STEP 1.B: VENIPUNCTURE WHOLE BLOOD**

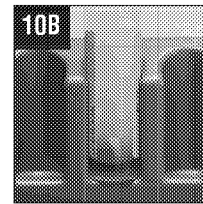
1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), or sodium citrate (light blue top). **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 2°-30°C (35°-86°F) for up to 5 days. Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
2. Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see picture 5B). Put the "rounded" end of the Loop into the tube of blood (see picture 6B). Make sure that the Loop is completely filled with blood (see picture 7B). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

**STEP 2: MIX**

1. Immediately insert the blood-filled end of the Loop all the way into the Vial (see picture 8B). Use the Loop to stir the blood sample in the Developer Solution ("Solution") (see picture 9B). Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.

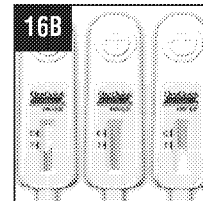
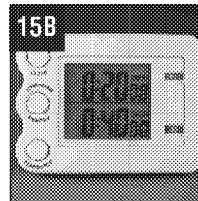
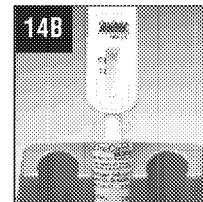
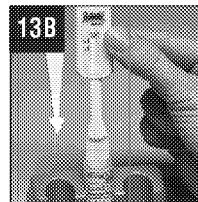
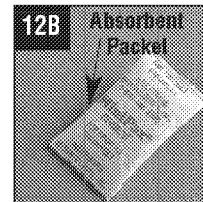
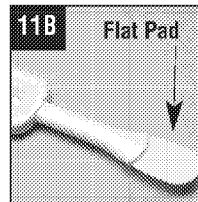


2. Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (*see picture 10B*). If the Solution is not pink, discard all test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.



STEP 3: TEST

1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture 11B*). Check to make sure that an Absorbent Packet is included with the Device (*see picture 12B*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
2. Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (*see picture 13B*). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (*see picture 14B*).
3. Start timing the test (*see picture 15B*). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (*see picture 16B*). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
4. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.

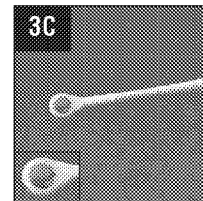
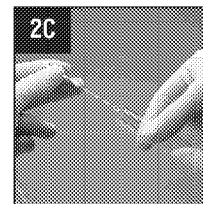
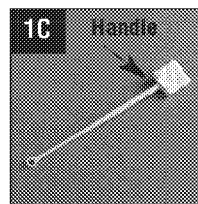


PLASMA PROCEDURE

NOTE: Testing of plasma samples may only be performed by laboratories certified to perform Moderate Complexity tests.

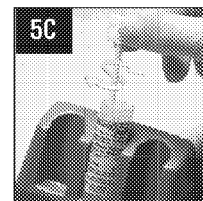
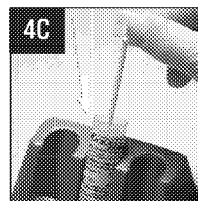
STEP 1: COLLECT

1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing EDTA (lavender top) anticoagulant. **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the specimen may be stored as whole blood for up to 5 days at 2°-30°C (35°-86°F) or as plasma for up to 7 days at 2°-8°C (35°-46°F).
2. Centrifuge the tube of blood [1000-1300 x g, for approximately 5 minutes, no refrigeration required] to separate the cells from the plasma. Carefully uncap the tube by gently rocking the stopper towards you so that it vents away from you.
3. Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (*see picture 1C*). Put the "rounded" end of the Loop into the tube of plasma (*see picture 2C*). Make sure that the Loop is completely filled with plasma (*see picture 3C*). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the plasma sample.



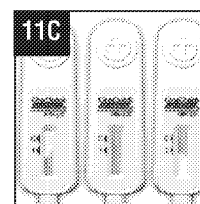
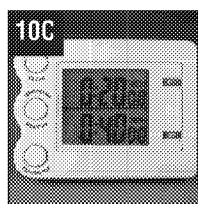
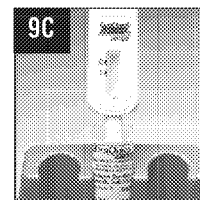
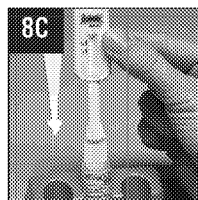
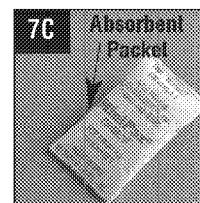
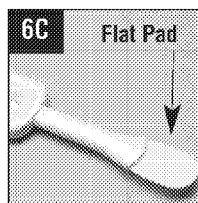
STEP 2: MIX

1. Immediately insert the plasma-filled end of the Loop all the way into the Vial (*see picture 4C*). Use the Loop to stir the plasma sample in the Developer Solution ("Solution") (*see picture 5C*). Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.



STEP 3: TEST

1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture 6C). Check to make sure that an Absorbent Packet is included with the Device (see picture 7C). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
2. Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see picture 8C). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 9C).
3. Start timing the test (see picture 10C). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 11C). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
4. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.

**GENERAL TEST CLEAN-UP**

1. Dispose of the used test materials in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

QUALITY CONTROL**Built-in Control Features**

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control ("C") area of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device. The Control line will appear on all valid tests, whether or not the sample is reactive or non-reactive. (Refer to *Test Result and Interpretation of Test Result* section below.)

External Quality Control

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls are available separately for use only with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. The HIV-1 and HIV-2 Positive Controls will produce a reactive test result and have been manufactured to produce a very faint Test ("T") line. The Negative Control will produce a non-reactive test result. (Refer to *Test Result and Interpretation of Test Result* section below.) Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°- 27°C (35°- 80°F),
- If the temperature of the testing area falls outside of 15°- 37°C (59°- 99°F), and
- At periodic intervals as dictated by the user facility.

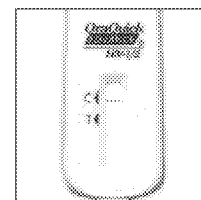
Refer to the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls package insert for instructions on the use of these reagents. It is the responsibility of each laboratory using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use. Contact OraSure Technologies' Customer Service if the Kit Control reagents do not produce the expected results.

TEST RESULT AND INTERPRETATION OF TEST RESULT**Refer to the Result Window on the Test Device.****NON-REACTIVE**

The diagram at the right shows an example of a **Non-Reactive** test result. A test is Non-Reactive if:

- a reddish-purple line appears next to the triangle labeled "C", **and NO** line appears next to the triangle labeled "T".

A **Non-Reactive** test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test result is interpreted as **NEGATIVE for HIV-1 and HIV-2 antibodies**. Follow CDC guidelines to inform the test subject of the test result and its interpretation.^{6,7}



REACTIVE

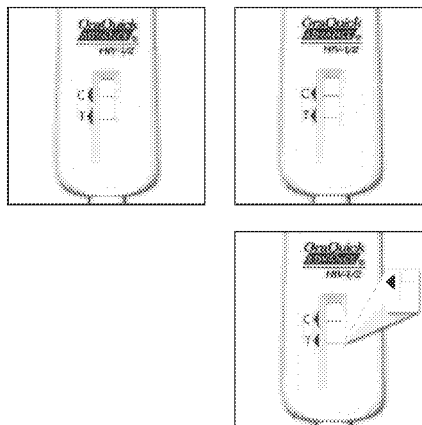
The diagrams at the right show examples of a **Reactive** test result.

A test is **Reactive** if:

- a reddish-purple line appears next to the triangle labeled "C" **and**
- a reddish-purple line appears next to the triangle labeled "T". One of these lines may be darker than the other.

NOTE: The test is **Reactive** if **any** reddish-purple line appears next to the "T" triangle **and** next to the "C" triangle, no matter how faint these lines are.

A **Reactive** test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as **PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies**. Follow CDC guidelines to inform the test subject of the test result and its interpretation.^{9,7}

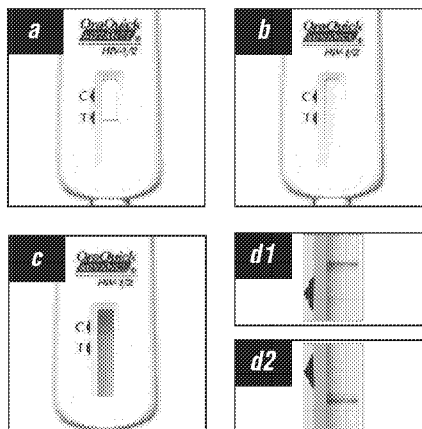
**INVALID**

The diagrams at the right show examples of an **Invalid** test result.

A test is **Invalid** if any of the following occurs:

- **NO** reddish-purple line appears next to the triangle labeled "C" (see picture *a* and *b*), or
- a red background in the Result Window makes it difficult to read the result after 20 minutes (see picture *c*), or
- if any of the lines are NOT inside the "C" or "T" triangle areas (see picture *d1* and *d2*)

An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Test Device. An **Invalid** result cannot be interpreted. **Repeat the test with a new Divided Pouch and a new oral fluid, fingerstick or venipuncture whole blood, or plasma sample. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.**

**LIMITATIONS OF THE TEST**

1. The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
3. This test is approved by FDA for use with oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens only. Use of other types of specimens, testing of venipuncture whole blood specimens collected using a tube containing an anticoagulant other than EDTA, sodium heparin, or sodium citrate, or testing of plasma specimens collected using a tube containing an anticoagulant other than EDTA may not yield accurate results.
4. Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.
5. Clinical data has not been collected to demonstrate the performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in persons under 12 years of age.
6. A reactive result using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen. OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
7. For a reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
8. A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
9. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

PERFORMANCE CHARACTERISTICS**SENSITIVITY****DETECTION OF ANTIBODIES TO HIV-1 IN SPECIMENS FROM INDIVIDUALS INFECTED WITH HIV-1****ORAL FLUID**

A sensitivity study was performed at eight clinical trial sites using freshly obtained oral fluid specimens collected from 767 individuals reported to be infected with HIV-1. Of the 767 specimens that were identified as seropositive using licensed confirmatory testing, 762 gave a reactive result on the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 1.

A separate study was performed at four clinical trial sites using freshly obtained oral fluid specimens collected from 3150 previously unscreened individuals from populations at high risk for HIV-1 infection. The results of this study are also shown in Table 1. Of the 73 specimens that were identified as seropositive using licensed confirmatory testing, 72 were reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

TABLE 1
Detection of Antibody to HIV-1 in Oral Fluid Specimens from HIV-1 Seropositive Individuals

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed EIA Repeatedly Reactive	True Positive ¹
Known HIV-1 Positive	767	762	764	767
High-Risk	3150	72 ²	74 ³	73
TOTAL	3917	834	838	840

¹ Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by licensed immunofluorescence assay (IFA).

² Eight additional specimens were OraQuick *ADVANCE*® false positive (see Table 7).

³ One specimen was EIA false positive, with a negative Western blot.

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be $834/840 = 99.3\%$ (95% C.I. = 98.4% - 99.7%).

PLASMA

A sensitivity study was performed at eleven clinical trial sites using EDTA-plasma specimens collected from 891 individuals reported to be infected with HIV-1. Of the 891 specimens that were identified as seropositive using licensed confirmatory testing, 887 gave a reactive result on the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 2.

A separate study was performed at six clinical trial sites using EDTA-plasma specimens collected from 533 previously unscreened individuals from populations at high risk for HIV-1 infection. The results of this study are also shown in Table 2. All of the 14 specimens that were identified as seropositive using licensed confirmatory testing, were reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

TABLE 2
Detection of Antibody to HIV-1 in Plasma Specimens from HIV-1 Seropositive Individuals

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed EIA Repeatedly Reactive	True Positive ¹
Known HIV-1 Positive	891	887	891	891
High-Risk	533	14 ²	14	14
TOTAL	1424	901	905	905

¹ Confirmation performed by licensed HIV-1 Western blot, confirmation of indeterminate Western blot results by radioimmunoprecipitation assay (RIPA) or licensed IFA.

² One additional specimen was OraQuick *ADVANCE*® false positive (see Table 8).

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be $901/905 = 99.6\%$ (95% C.I. = 98.9% - 99.8%).

FINGERSTICK WHOLE BLOOD

A sensitivity study was performed at eight clinical trial sites using freshly obtained fingerstick whole blood samples from 481 individuals known to be infected with HIV-1 and 40 AIDS patients. Of the 521 specimens that were repeatedly reactive using a licensed EIA and positive by Western blot, 519 gave a reactive result on the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 3.

A separate study was performed at seven clinical trial sites using 625 freshly obtained fingerstick whole blood samples from previously unscreened individuals from populations at high risk for HIV-1 infection. The results of this study are also shown in Table 3. Of the 625 specimens tested, 20 were repeatedly reactive using a licensed EIA, of which 17 were positive by Western blot. These same 17 specimens gave a reactive result using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

TABLE 3
Detection of Antibody to HIV-1 in Fingerstick Whole Blood Samples from Patients with AIDS and from HIV-1 Seropositive Individuals

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed EIA Repeatedly Reactive	True Positive ¹
AIDS	40	40	40	40
Known HIV-1 Positive	481	479	481	481
High-Risk	625	17	20 ²	17
TOTAL	1146	536	541	538

¹ Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by RIPA.

² Two specimens were negative and one was indeterminate on Western blot with a negative RIPA.

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be 536/538 = 99.6% (95% C.I. = 98.5% - 99.9%).

Reactivity with HIV-1 Specimens From Various Geographic Regions

To assess the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test for HIV-1 variants from various geographic regions, 215 confirmed HIV-1 antibody-positive serum/plasma specimens were obtained from various parts of the world. Of these 215 specimens, 214 were reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. One confirmed HIV-1 antibody-positive specimen from China was non-reactive using the OraQuick *ADVANCE*® test. An additional 13 specimens representing HIV-1 Subtypes A, B, C, D, F, and G, and Group O were tested and reactive on OraQuick *ADVANCE*®.

Reactivity with HIV-1 Seroconversion Panels

Eleven HIV-1 seroconversion panels were tested in comparison with licensed anti-HIV EIA tests. Each panel consisted of sequential serum/plasma specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of 69 specimens. The results of this study are shown in Table 4. In this study, the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was demonstrated to be capable of detecting seroconversion similar to currently available FDA licensed EIAs.

TABLE 4
Comparison of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests
Using Seroconversion Panels

Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Relative Day of Bleed	OraQuick <i>ADVANCE</i> ® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
K	1	NR	NR	NR	NR	NR	NR
	7	NR	NR	NR	NR	NR	NR
	9	NR	NR	NR	NR	NR	NR
	14	R	NR	RR	NR	NR	NR
	16	R	NR	RR	NR	NR	NR
	21	R	NR	RR	NR	RR	RR
	23	R	RR	RR	RR	RR	RR
	30	R	RR	RR	RR	RR	RR
	34	R	RR	RR	RR	RR	RR
	37	R	RR	RR	RR	RR	RR
N	1	R	RR	RR	NR	NR	NR
	5	R	RR	RR	NR	RR	NR
	8	R	RR	RR	NR	RR	NR
	26	R	RR	RR	RR	RR	RR
	32	R	RR	RR	RR	RR	RR
Q	1	NR	NR	NR	NR	NR	NR
	54	NR	NR	NR	NR	NR	NR
	58	NR	NR	NR	NR	NR	NR
	61	NR	NR	RR	NR	NR	NR
	66	R	NR	RR	NR	NR	NR
	68	R	RR	RR	NR	NR	NR
	73	R	RR	RR	RR	RR	RR
R (M)	3	NR	NR	RR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	14	R	RR	RR	RR	RR	RR
	16	R	RR	RR	RR	RR	RR
	22	R	RR	RR	RR	RR	RR
S	1	NR	NR	NR	NR	NR	NR
	10	R	RR	RR	NR	NR	NR
	12	R	RR	RR	NR	RR	NR
W	1	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	13	NR	NR	NR	NR	NR	NR
	15	NR	NR	NR	NR	NR	NR
	29	NR	NR	NR	NR	NR	NR
	31	NR	NR	NR	NR	NR	NR
	36	NR	NR	NR	NR	NR	NR
	38	NR	NR	NR	NR	NR	NR
	48	NR	NR	RR	NR	NR	NR
	85	R	RR	RR	RR	RR	RR
	87	R	RR	RR	RR	RR	RR
	146	R	RR	RR	RR	RR	RR
	162	R	RR	RR	RR	RR	RR
AB	1	NR	NR	NR	NR	NR	NR
	29	NR	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	NR	NR
	36	R	RR	RR	NR	NR	RR
	41	R	RR	RR	RR	RR	RR

Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Relative Day of Bleed	OraQuick ADVANCE® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
AC	1	NR	NR	NR	NR	NR	NR
	112	NR	NR	RR	NR	NR	NR
	121	R	RR	RR	RR	RR	RR
	126	R	RR	RR	RR	RR	RR
	131	R	RR	RR	RR	RR	RR
AE	1	NR	NR	NR	NR	NR	NR
	4	NR	NR	NR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	11	NR	RR	RR	NR	RR	NR
AF	1	NR	NR	NR	NR	NR	NR
	3	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	10	NR	NR	NR	NR	NR	NR
	16	NR	NR	NR	NR	NR	NR
	29	R	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	RR	RR
	36	R	RR	RR	RR	RR	RR
AI	1	NR	NR	NR	NR	NR	NR
	8	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	RR	RR

NR = Non-Reactive; R = Reactive; RR = Repeatedly Reactive

Reactivity with HIV-1 Low Titer Panels

Two low titer HIV-1 antibody panels were tested in comparison with licensed anti-HIV EIA tests. The low titer antibody panels consisted of 30 serum/plasma specimens. The results of this study are shown in Table 5. In this study, the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test was demonstrated to be capable of detecting antibodies to HIV-1 similar to currently available FDA licensed EIAs.

TABLE 5
Comparison of the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests
Using Low Titer HIV-1 Antibody Panels

Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Member	OraQuick ADVANCE® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
LT106	1	R	RR	RR	RR	RR	RR
	2	NR	NR	RR	NR	NR	NR
	3	R	RR	RR	RR	RR	RR
	4	R	RR	RR	RR	RR	RR
	5	R	RR	RR	RR	RR	RR
	6	NR	NR	NR	NR	NR	NR
	7	R	RR	RR	RR	RR	RR
	8	NR	RR	RR	NR	NR	NR
	9	R	RR	RR	RR	RR	RR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	NR	RR
	13	R	RR	RR	RR	RR	RR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

Specimen Information		Licensed Anti-HIV EIA Tests					
Panel	Member	OraQuick ADVANCE® Test	EIA #1	EIA #2	EIA #3	EIA #4	EIA #5
LT107	1	NR	NR	RR	RR	NR	NR
	2	R	NR	RR	RR	RR	NR
	3	R	NR	RR	NR	NR	NR
	4	R	RR	RR	RR	RR	NR
	5	NR	NR	NR	NR	NR	NR
	6	R	RR	RR	RR	RR	NR
	7	NR	NR	RR	RR	NR	NR
	8	NR	NR	RR	NR	RR	NR
	9	NR	NR	RR	NR	NR	NR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	RR	RR	RR
	12	NR	NR	RR	NR	NR	NR
	13	NR	NR	RR	RR	NR	NR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

NR = Non-Reactive; R = Reactive; RR = Repeatedly Reactive

Interfering Substances and Unrelated Medical Conditions

To assess the impact of unrelated medical conditions or interfering substances on the sensitivity of the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, 200 serum/plasma specimens from a variety of medical conditions unrelated to HIV-1 infection and 125 specimens with interfering substances were spiked with an HIV-1 positive specimen to give a level of reactivity in the low positive range (see list of medical conditions and interfering substances in Table 10 below). All spiked specimens gave reactive results.

In addition, a study was performed to assess the potential effect of anticoagulants on assay sensitivity. Venipuncture whole blood collected from 24 subjects, in each of 3 tubes containing one of three anticoagulants (EDTA, sodium heparin, and sodium citrate) was spiked with an HIV-1 positive specimen or an HIV-2 positive specimen to give a level of reactivity in the low positive range. The HIV-1 positive samples and the HIV-2 positive samples were then aliquoted and stored refrigerated (2°-8°C), at room temperature (18°C) or at elevated temperatures (30-33°C) and tested over a 7-day period. There was no anticoagulant-specific effect observed on assay performance with samples held up to 7 days at 2°-30°C.

As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, mouthwash within 24 hours of testing, concomitant medications, dental fixtures, and food or drink immediately prior to testing). None of these disease states, medical conditions or other factors interfered with test sensitivity. In a separate study of 40 individuals, consumption of alcohol, brushing of teeth, use of mouthwash or smoking tobacco 5 minutes prior to testing, were shown to have no effect on test sensitivity.

DETECTION OF ANTIBODIES TO HIV-2 IN SPECIMENS FROM INDIVIDUALS INFECTED WITH HIV-2

A total of 324 serum/plasma specimens reported to be HIV-2 antibody positive were obtained from various repository sources. Specimens were tested by licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA, licensed HIV-1 Western blot, an HIV-2 Western blot and HIV-2 specific PCR. A total of 6 specimens were not demonstrated to be positive for antibodies to HIV-1 or HIV-2, all of which were OraQuick ADVANCE® non-reactive. Two of the 6 negative specimens were repeatedly reactive by licensed anti-HIV-1/2 EIA, negative by licensed anti-HIV-2 EIA, and indeterminate by licensed HIV-1 Western blot and by an HIV-2 Western blot.

Of the remaining 318 specimens, 151 were positive on an HIV-2 Western blot and 50 were positive using an HIV-2 specific PCR. One hundred and twenty-two specimens gave confirmatory results consistent with HIV-1 infection and were excluded from the analysis. One specimen was categorized as a dual infection based on additional testing by co-culture, and was not included in the sensitivity analysis. One specimen, while indeterminate on HIV-1 and HIV-2 Western blots, gave a positive result on an HIV-2 radioimmuno-precipitation assay (RIPA) and is also considered to be positive for antibodies to HIV-2. OraQuick ADVANCE® detected 201/201 (100%) of the specimens from individuals confirmed as positive for HIV-2 antibodies (see Table 6).

In a separate study, a total of 499 plasma specimens collected from an HIV-2 endemic area (Ivory Coast) were prepared as contrived whole blood and tested by OraQuick ADVANCE®, licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA, licensed HIV-1 Western blot, and an HIV-2 Western blot. Table 6 shows a summary of the results. OraQuick ADVANCE® was reactive with all of the 27 specimens that were repeatedly reactive by licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA and positive on licensed HIV-1 Western blot, and with all three specimens that were confirmed as positive for HIV-2 only by an HIV-2 Western blot. Two specimens were OraQuick ADVANCE® false positive.

TABLE 6
Detection of Antibody to HIV-2 in Samples from HIV-2 Seropositive Individuals and
Individuals at High Risk of HIV-2 Infection

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Reactive	Licensed anti-HIV-2 EIA Repeatedly Reactive or HIV-2 PCR Positive	True HIV-2 Positive ¹
Known HIV-2 Positive	324 ²	201	201 ³	201 ⁴
High-Risk	499	32	33	3
TOTAL	823	233	234	204

¹ Confirmation performed by HIV-2 Western blot, with RIPA confirmation of Indeterminate Western blot results.

² One hundred and twenty-two specimens gave confirmatory results consistent with HIV-1 infection and were excluded from the analysis. In addition, one specimen was categorized as a dual infection based on additional testing by co-culture, and was not included in the sensitivity analysis.

³ 151 specimens were tested with an anti-HIV-2 EIA alone. HIV-2 DNA or RNA PCR was performed on the remaining 50 specimens instead of EIA. All results were positive.

⁴ One specimen was confirmed to be HIV-2 positive based on the positive results of an HIV-2 specific RIPA.

Combining the number of OraQuick *ADVANCE*® reactive results obtained from the study of confirmed positives with the number of OraQuick *ADVANCE*® reactive results obtained from the study of the high risk population, the sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test for the detection of antibodies to HIV-2 in these studies was calculated to be 204/204 = 100% (95% C.I. = 98.2% - 100%).

In addition, 3 HIV-2 infected individuals located in the USA were tested by fingerstick whole blood and oral fluid OraQuick *ADVANCE*® tests. Fingerstick whole blood and oral fluid samples from all three subjects were reactive on the OraQuick *ADVANCE*® test.

SPECIFICITY

ORAL FLUID

A specificity study was performed at four clinical trial sites using freshly obtained oral fluid specimens collected from 605 previously unscreened individuals at low risk for HIV-1 infection. All of the 605 specimens were correctly non-reactive using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. Of the 3077 HIV antibody-negative specimens from the four study sites that examined populations at high risk for HIV-1 infection, the OraQuick *ADVANCE*® test was non-reactive for 3069. The results are summarized in Table 7.

TABLE 7
Performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test on Oral Fluid Specimens
from Individuals Presumed to be Negative for HIV Infection

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Non-Reactive	Licensed EIA Non-Reactive	True Negative ¹
Low-Risk	605	605	599 ²	605
High-Risk	3150	3069 ³	3076 ⁴	3077
TOTAL	3755	3674	3675	3682

¹ Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by RIPA or IFA.

² Six specimens were EIA false positive, five with a negative Western blot and one with an indeterminate blot which was confirmed negative by IFA.

³ One additional specimen was OraQuick *ADVANCE*® false negative (see Table 1).

⁴ One specimen was EIA false positive with a negative Western blot.

Combining the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the low-risk populations with the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the high-risk populations, the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be 3674/3682 = 99.8% (95% C.I. = 99.6% - 99.9%).

PLASMA

A specificity study was performed at seven clinical trial sites using EDTA-plasma specimens collected from 1102 previously unscreened individuals at low risk for HIV infection. All of the specimens, except for one, gave non-reactive results using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. In addition, 519 of the 520 HIV antibody-negative specimens from study sites that examined populations at high risk for HIV-1 infection also gave non-reactive results using the OraQuick *ADVANCE*® test. The results of this study are shown in Table 8.

TABLE 8
Performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test on Plasma Specimens
from Individuals Presumed to be Negative for HIV Infection

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Non-Reactive	Licensed EIA Non-Reactive	True Negative ¹
Low-Risk	1102	1101	1096 ²	1102
High-Risk	534	519	516 ³	520
TOTAL	1636	1620	1612	1622

¹ Confirmation performed by licensed HIV-1 Western blot, with confirmation of indeterminate Western blot results by RIPA or IFA.

² Six specimens were EIA false positive, five with a negative Western blot and one with an indeterminate blot which was confirmed negative by IFA.

³ Four specimens were EIA false positive, with 1 negative and 3 indeterminate by Western blot, that confirmed negative by IFA.

Combining the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the low-risk populations with the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the high-risk populations, the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be $1620/1622 = 99.9\%$ (95% C.I. = 99.6% - 99.9%).

FINGERSTICK WHOLE BLOOD

A specificity study was performed at eight clinical trial sites using freshly obtained fingerstick whole blood samples from 1250 previously unscreened individuals at low risk for HIV-1 infection. In the course of this study, two specimens were confirmed to have antibodies to HIV-1 and were removed from the specificity calculation. All of the remaining specimens gave non-reactive results using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. In addition, all of the 608 HIV-1 antibody-negative specimens from the study sites that examined populations at high risk for HIV-1 infection also gave non-reactive results using the OraQuick *ADVANCE*® test. The results of this study are shown in Table 9.

TABLE 9
Performance of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test on Fingerstick Whole Blood Specimens
from Individuals Presumed to be Negative for HIV Infection

Test Group	Total Samples	OraQuick <i>ADVANCE</i> ® Non-Reactive	Licensed EIA Non-Reactive	True Negative ³
Low-Risk	1250 ¹	1248	1247 ²	1248
High-Risk	625	608	605	608
TOTAL	1875	1856	1852	1856

¹ Two specimens in the low-risk study that gave reactive results using the OraQuick *ADVANCE*® test, repeatedly reactive results using a licensed EIA, and positive results using a licensed Western blot were removed from the calculation of specificity.

² One specimen was EIA repeatedly reactive, Western blot negative.

³ True negative status based on negative or indeterminate test results using a licensed Western blot.

Combining the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the low-risk populations with the number of OraQuick *ADVANCE*® non-reactive results obtained from the study of the high-risk populations, the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in these studies was calculated to be $1856/1856 = 100\%$ (95% C.I. = 99.7% - 100%).

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

To assess the impact of unrelated medical conditions or interfering substances on the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 321 serum/plasma specimens from a variety of medical conditions unrelated to HIV infection and 119 specimens with interfering substances were analyzed. The results of this study are shown in Table 10. One specimen from subjects known to be positive for EBV, for HBV, or for rheumatoid factor, one from a multiparous woman, and three specimens from known HAV infected subjects gave false positive results.

In addition, a study was performed to assess the potential effect of anticoagulants on assay specificity. Venipuncture whole blood was collected from 24 HIV negative subjects, in each of 3 tubes containing one of the following anticoagulants: EDTA, sodium heparin, and sodium citrate. The samples were then aliquoted and stored either refrigerated (2°-8°C), at room temperature (18°C) or at elevated temperatures (30-33°C) and tested over a 7-day period. There was no anticoagulant-specific effect observed on assay performance with samples held up to 5 days at 2-30°C (refer to Table 10).

TABLE 10
OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Reactivity with Specimens from Individuals with Potentially Interfering Medical Conditions and Specimens with Interfering Substances

Medical Condition (n = 321)	OraQuick ADVANCE® Results	
	Reactive	Non-Reactive
Multiparous women	1 ²	14
Anti-nuclear antibody (ANA)	0	17
Lupus	0	15
Rheumatoid factor	1 ²	17
Cytomegalovirus (CMV)	0	15
Epstein Barr virus (EBV)	1 ²	14
Hepatitis A virus (HAV)	3 ¹	17
Hepatitis B virus (HBV)	1 ²	16
Hepatitis C virus (HCV)	0	15
Human T-cell Lymphotropic virus Type I (HTLV-I)	0	15
Human T-cell Lymphotropic virus Type II (HTLV-II)	0	15
Rubella	0	15
IgG gammopathies	0	13
IgM gammopathies	0	12
Syphilis	0	15
Toxoplasmosis	0	15
Tuberculosis	0	15
Influenza	0	10
Multiple transfusions	0	10
Hemophiliac	0	10
Herpes Simplex virus	0	5
Cirrhosis	0	5
Dialysis patient	0	4
Colon cancer	0	4
HTLV I/II	0	2
Chlamydia	0	3
Anti-scl or anti-rnp antibody	0	3
Breast cancer	0	1
Anti-DNA antibody	0	1
Gonorrhea	0	1
Interfering Substances (n = 211)		
Elevated Bilirubin	0	20
Elevated Hemoglobin	0	20
Elevated Triglycerides	0	20
Elevated Protein	0	20
Bacterially Contaminated	0	25
Visual Hemolysis (hemolytic)	0	5
Icteric	0	5
Lipemic	0	4
Sodium Heparin ³	0	24
EDTA ³	0	24
Sodium Citrate ³	0	24

¹ A total of 3 of the 20 HAV specimens were OraQuick ADVANCE® falsely reactive. Two of the 3 specimens were OraQuick ADVANCE® non-reactive at the 20-25 minute read time and reactive at the 55-60 minute read time. The remaining specimen was reactive at both read times.

² One of the specimens was OraQuick ADVANCE® non-reactive at the 20-25 minute read time and reactive at the 55-60 minute read time.

³ The OraQuick ADVANCE® assay maximum read time for these specimens was 40 minutes. Based upon specimen storage for 5 days at 2-30°C.

As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, mouthwash within 24 hours of testing, concomitant medications, dental fixtures, and food or drink immediately prior to testing). None of these disease states, medical conditions or other factors interfered with test specificity. In a separate study of 40 individuals, consumption of alcohol, brushing of teeth, use of mouthwash or smoking tobacco 5 minutes prior to testing, were shown to have no effect on test specificity.

REPRODUCIBILITY

The reproducibility of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was tested at 3 sites using 3 lots of the device on 3 different days with 9 operators (3 per site). A blind-coded panel was tested that consisted of 5 contrived blood specimens (4 antibody-positive and 1 antibody-negative). Test results were recorded at 20-25 minutes and at 55-60 minutes. A total of 405 tests were performed (135/site), with a total of 81 tests per panel member. The overall reproducibility of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test was 405/405 = 100%. Concordance between the specified assay read time limits was 99.8% (404/405); a single HIV-1 low positive panel member that was non-reactive at the 20-25 minute read time was reactive at the 55-60 minute read time.

RESULTS OF UNTRAINED USER STUDY

An "Untrained User" study was conducted in which participants were given only the test instructions and asked to perform testing of a blinded panel comprised of 6 randomized specimens of three different levels (Negative, Low Positive and High Positive OraQuick *ADVANCE*® test reactivity) consisting of human plasma. The participants were not given any training on the use of the test or the interpretation of the test results, nor were they allowed to observe the performance of the Kit Controls by the Study Coordinator. The study protocol stipulated that professionally trained medical laboratory personnel or persons with prior experience using the OraQuick *ADVANCE*® device were excluded from participation. A total of 100 participants were enrolled from a total of four sites, representing a diverse demographic (educational, ethnic, age, gender, etc.) population.











The rate of correct results for the overall study was 98.6% (592/600). Refer to the table below for a summary of the performance relative to the specimen type. The eight incorrect results were attributed to six participants. Of these six participants, four obtained 5 out of 6 correct results, and two participants obtained 4 out of 6 correct results.

Untrained Users Rate of Correct Test Results			
Negative	Low Positive	High Positive	Total
98.5% (197/200) 95% C.I. (95.7% - 99.7%)	98.0% (196/200) 95% C.I. (95.0% - 99.5%)	99.5% (199/200) 95% C.I. (97.3% - 99.9%)	98.6% (592/600) 95% C.I. (97.4% - 99.4%)

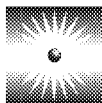
There were 1.7% (10/600) Invalid results reported, with 5 of the 10 Invalid results attributed to one participant. All tests were successfully repeated, with 8/10 of the repeat test results interpreted correctly. The 2 incorrect repeat results were attributed to one participant. While most participants were able to obtain valid results with the first attempt, one of the 100 participants experienced five Invalid test results out of six tests performed. Operator error was observed in some cases to be attributed to specimen vial mix-ups. These findings support the need for training of non-laboratory personnel in the handling of multiple samples in a laboratory setting where specimens are tested in batch mode. As part of the Untrained User study, a Participant Feedback Questionnaire was completed. All participants rated the test as 'easy to use' and felt 'able to perform the test correctly'.

BIBLIOGRAPHY

1. Gallo RC, Salahuddin SZ, Popovic M, et al. Frequent detection and isolation of cytopathic retroviruses (HTLV III) from patients with AIDS and at risk for AIDS. *Science* 1984; 224:500-3.
2. Curran JW, Morgan WM, Hardy AM, et al. The epidemiology of AIDS: current status and future prospects. *Science* 1985; 229:1352-7.
3. Clavel F, Guetard D, Brun-Vezinet F, et al. Isolation of a new human retrovirus from West African patients with AIDS. *Science* 1986; 233:343-6.
4. Sehulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. *Appl Env Microbiol* 1981; 42:762-7.
5. CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR* 1988; 37(24):377-388.
6. CDC. Approval of a New Rapid Test for HIV Antibody. *MMWR* 2002; 51(46):1051-1052 and Erratum 51(47):1075.
7. CDC: Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women. *MMWR* 2001; 50(19):32-35.
8. CDC: Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 2001; 50(RR-11):1-42.
9. CDC. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *HICPAC* 2007; 12-93.

EXPLANATION OF SYMBOLS			
	Batch Code		<i>In Vitro</i> Diagnostic Medical Device
	Catalog Number		Manufacturer
	Caution, Consult Accompanying Documents		Temperature Limitation
	HIV Negative Control		Use By
	HIV-1 Positive Control		HIV-2 Positive Control

Manufactured by



OraSure Technologies, Inc.

220 East First Street, Bethlehem, PA 18015
 1- (800) ORASURE (600-672-7873) or 610-882-1820
www.orasure.com

Item #3001-1215 rev. 05/11

EXHIBIT 7



Multispot HIV-1/HIV-2 Rapid Test

Rapid Enzyme Immunoassay to be used as a diagnostic aid for the detection and differentiation of HIV-1 and HIV-2 antibodies in human serum or plasma.

For *In Vitro* Diagnostic Use

25228 • 50 Tests

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7. REAGENT PREPARATION AND STORAGE
8. SPECIMEN COLLECTION, PREPARATION, AND STORAGE
9. MULTISPOT HIV-1/HIV-2 RAPID TEST PROCEDURE
10. QUALITY CONTROL - VALIDATION OF RESULTS
11. TEST RESULT APPEARANCE AND INTERPRETATION – RAPID HIV-1/HIV-2 TESTING
12. LIMITATIONS OF THE PROCEDURE
13. EXPECTED PERFORMANCE CHARACTERISTICS – RAPID HIV-1/HIV-2 TESTING
14. USE OF MULTISPOT AS AN ANTIBODY DIFFERENTIATION ASSAY IN A DIAGNOSTIC TESTING ALGORITHM
15. PERFORMANCE CHARACTERISTICS OF MULTISPOT IN A DIAGNOSTIC TESTING ALGORITHM
16. BIBLIOGRAPHY

This package insert must be read completely before performing the test. Failure to follow the insert may give inaccurate test results. Users of this test should follow the CDC Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens.¹

Complexity: Moderate

1 - NAME AND INTENDED USE

The Multispot HIV-1/HIV-2 Rapid Test is a single use qualitative immunoassay to detect and differentiate circulating antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1, HIV-2) in fresh or frozen human serum and plasma. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in fresh or frozen human serum or plasma. This test is suitable for use in multi-test algorithms designed for statistical validation of an HIV screening test result or as part of an HIV-1/HIV-2 diagnostic testing algorithm that includes differentiation of HIV-1 and HIV-2 antibodies.

RESTRICTIONS

- **Sale of the Multispot HIV-1/HIV-2 Rapid Test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.**
- **The Multispot HIV-1/HIV-2 Rapid Test is approved for use only by an agent of a clinical laboratory.**
- **Test subjects must receive the "Subject Information Notice" prior to specimen collection, and appropriate information when test results are provided, unless this test is used as part of a multi-test diagnostic algorithm.**
- **The Multispot HIV-1/HIV-2 Rapid Test is not approved for use to screen blood, plasma, cell, or tissue donors.**

2 - SUMMARY AND EXPLANATION OF THE TEST

Acquired Immunodeficiency Syndrome (AIDS) is caused by viruses transmitted by sexual contact, exposure to blood (including sharing contaminated needles and syringes) or certain blood products, or transmitted from an infected mother to her fetus or child during the perinatal period.² Additionally, transmission of the viruses can occur through tissue transplantation.³ Human Immunodeficiency Virus Type 1 (HIV-1) has been isolated from patients with AIDS and AIDS-related complex (ARC).⁴⁻⁶ HIV-1 was thought to be the sole causative agent of these syndromes until 1986, when a second type of Human Immunodeficiency Virus (Human Immunodeficiency Virus Type 2 or HIV-2) was isolated and also reported to cause AIDS.⁷⁻⁸ Since the initial discovery, hundreds of cases of HIV-2 infection have been documented worldwide.⁹ In the United States, there have been more than 80 cases of infection with HIV-2 reported, including two blood donors.¹⁰⁻¹⁵

This second immunodeficiency virus (HIV-2) is similar to, but distinct from, HIV-1. Both viruses have similar morphology and lymphotropism,¹⁶ and the modes of transmission appear to be identical.^{9,17} The HIV-1 and HIV-2 genomes exhibit about 60% homology in conserved genes such as gag and pol, and 39-45% homology in the envelope genes.¹⁸ Serologic studies have also shown that the core proteins of HIV-1 and HIV-2 display frequent cross-reactivity whereas the envelope proteins are more type-specific.¹⁹

Within the two major HIV types, there is significant variation, as well. By analyzing sequences of representative strains, HIV-1 has been divided into three groups: group M (for major), including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non-O).²⁰⁻²² Similarly, the HIV-2 strains have been classified into at least five subtypes (A through E).²³ Some HIV-1 variants share ≤50% homology in their envelope genes with the sequences of more common prototype strains.

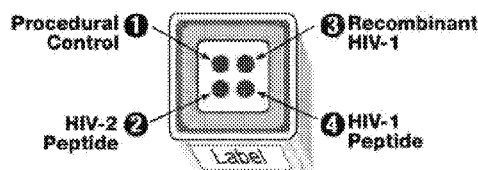
Despite some degree of immunological cross-reactivity between types and subtypes of HIV, reliable detection of antibodies derived from the more divergent strains may only be achieved by incorporating type-specific protein sequences into the assay design. In one study, detection of HIV-2 positive samples by HIV-1 antibody kits ranged from 60% to 91%, depending on the test used.²⁴ The Multispot HIV-1/HIV-2 Rapid Test incorporates highly conserved recombinant and synthetic peptide sequences representing HIV-1 and HIV-2 envelope proteins.²⁵⁻³¹ The Multispot HIV-1/HIV-2 Rapid Test is designed to detect antibodies to HIV-1 and HIV-2 in serum or plasma rapidly and reliably without instrumentation. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results or as part of an HIV-1/HIV-2 diagnostic testing algorithm that includes differentiation of HIV-1 and HIV-2 antibodies.³²⁻³⁸

3 - BIOLOGICAL PRINCIPLE OF THE TEST

The Multispot HIV-1/HIV-2 Rapid Test is based on the principle of ImmunoConcentration™.³⁹ The Multispot HIV-1/HIV-2 Cartridge contains a removable specimen prefilter, the reaction membrane, and an absorbent pad. All of the liquids added to the Cartridge are absorbed by the pad and contained within the Cartridge. When the test is completed, the entire Cartridge can be decontaminated by standard laboratory practices (see Precautions For Users) and properly discarded.

Microscopic particles are separately coated with the antigens that represent portions of the transmembrane proteins HIV-1 and HIV-2, respectively. The microparticles are immobilized on the reaction membrane of the Multispot HIV-1/HIV-2 Cartridge and form the Test Spots. The reaction membrane also contains a Procedural Control Spot that serves as a control spot to ensure that the entire test procedure was properly executed. Samples to be tested are diluted in Specimen Diluent and then added to the prefilter in the Cartridge. After the diluted specimen has been completely absorbed, the prefilter is removed. If antibodies against HIV-1 and/or HIV-2 are present in the specimen, they bind to the antigens on the microparticles in the specific spots on the cartridge membrane. The Conjugate, which contains alkaline phosphatase-labeled goat anti-human IgG (H+L chain specific), is then added to the Cartridge. The Conjugate binds to the human antibody-antigen complexes that are immobilized in the spots on the cartridge membrane. Unbound Conjugate is removed by a wash step.

Next, Development Reagent is added to the Cartridge. A purple color develops on the Test Spots in proportion to the amount of antibodies against HIV-1 and/or HIV-2 that have been bound to the antigen-coated microparticles and detected by the Conjugate. A purple color will also develop on the Procedural Control Spot when the test has been performed correctly. Color development is stopped by the addition of Stop Solution. The membrane is examined visually for the presence of purple color on the Procedural Control Spot and on the Test Spots.



- ① Procedural Control: Anti-human IgG (goat)
- ② HIV-2 Peptide: Peptide representing the immunodominant epitope of the HIV-2 virus gp36 envelope glycoprotein
- ③ Recombinant HIV-1: Recombinant gp41 (HIV-1 envelope glycoprotein) expressed in *E. coli* (gp41 rDNA)
- ④ HIV-1 Peptide: Peptide representing the immunodominant epitope of the HIV-1 virus gp41 envelope glycoprotein

4- REAGENTS

MULTISPOT HIV-1/HIV-2 Rapid Test
Product No. 25228 (50 Tests)

Component	Contents	Preparation
1 • Multispot HIV-1/HIV-2 Cartridge (50)	• Foil-sealed base container with specimen prefilter; Membrane with 1 Procedural Control Spot and 3 Test Spots	Remove foil seal before use.
2 • Positive Control Serum 1 dropper bottle (1 mL)	• Heat-inactivated human serum/plasma containing anti-HIV-1 and anti-HIV-2 immunoglobulin; Nonreactive for HBsAg and antibody to HCV • 0.1% Sodium azide • 0.5% ProClin™ 300	Dilute in Specimen Diluent as described.
3 • Negative Control Serum 1 dropper bottle (1 mL)	• Human serum; Nonreactive for HBsAg and antibody to HIV and HCV • 0.1% Sodium azide • 0.5% ProClin™ 300	Dilute in Specimen Diluent as described.
4 • Specimen Diluent 1 dropper bottle (25 mL)	• Diluent for specimens and Controls • 0.1% ProClin™ 150 • 0.125% ProClin™ 300	Dispense with dropper provided.
5 • Conjugate 1 dropper bottle (9.5 mL)	• Anti-human IgG (H+L) (goat) alkaline phosphatase conjugated solution • 0.1% ProClin™ 150	Ready to use as supplied.
6 • Wash Solution 2 dropper bottles (2 x 85 mL)	• TRIS • Urea • Propylene glycol • Nitroblue tetrazolium • 0.1% ProClin™ 150	Ready to use as supplied.
7 • Development Reagent 1 dropper bottle (8.5 mL)	• 3-Indoxyl phosphate	Ready to use as supplied.
8 • Stop Solution 1 dropper bottle (55 mL)	• 0.1 N H ₂ SO ₄ (sulfuric acid)	Ready to use as supplied.
9 • Disposable Transfer Pipets (60)	• Polyethylene transfer pipets	Ready to use as supplied.
10 • Eyedropper (1)	• Polyethylene eyedropper and cap with rubber bulb; Contains Dry Natural Rubber, a potential sensitizer	Use in Specimen Diluent bottle.

5 - WARNINGS FOR USERS**For In Vitro Diagnostic Use**

1. This package insert must be read completely before performing the test. Failure to follow the insert may give inaccurate test results.
2. **This kit has been approved for use with serum and plasma specimens only. Use of this test kit with specimens other than those specifically approved for use with this test kit may result in inaccurate test results.**
3. Bring all reagents to room temperature (20-30°C) before use.
4. **The following is a list of potential chemical hazards contained in some kit components (refer to product REAGENTS chart):**



- a. **WARNING:** Some reagents contain 0.1% ProClin 150 or 0.5% ProClin 300:
H317: May cause an allergic skin reaction.
P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.

P501: Dispose of contents and container in accordance to local, regional, national and international regulations.

ProClin 300 (0.1% ProClin 150 and 0.5% ProClin 300) are biocidal preservatives that are irritating to eyes and skin, may be detrimental if enough is ingested, and may cause sensitization by skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

- b. **WARNING:** Some reagents contain **0.1% Sodium Azide [NaN₃]:**

H303: May be harmful if swallowed.

H313: May be harmful in contact with skin.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

Sodium azide may react with lead and copper plumbing to form metal azides that are highly explosive. If disposed of in the sink, flush plumbing with a large volume of water to prevent azide buildup.

- c. **The dilute 0.1 N sulfuric acid (H₂SO₄) Stop Solution may be detrimental if swallowed and by contact, particularly to eyes.** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wastes can typically be neutralized to pH 6-8 for disposal if trained and equipped to do so, however always dispose of dilute acidic / corrosive solutions in accordance with local, regional, national and international regulations. Do not pour water into this product.

5. Users of this test should follow the CDC Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens.¹

6. **The Multispot HIV-1/HIV-2 Rapid Test contains human blood components.** No known test method can offer complete assurance that infectious agents are absent. Therefore, all human blood derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended *Universal Precautions* for bloodborne pathogens as defined by OSHA, Biosafety Level 2 guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*⁽⁴⁰⁾, WHO *Laboratory Biosafety Manual*⁽⁴¹⁾, and/or local, regional and national regulations. The following human blood derivatives are found in this kit:



- a. **The Positive Control Serum has been heat-treated to inactivate HIV viruses** and has been tested and found nonreactive for Hepatitis B Surface Antigen (HBsAg) and antibodies to Hepatitis C virus (HCV Ab).
- b. **The human source material used in the preparation of the Negative Control Serum** has been tested and found nonreactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C virus (HCV Ab), and antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2 Ab).

Biological spills: Human source material spills should be treated as potentially infectious.

Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment with an appropriate chemical disinfectant that is effective for the potential biohazards relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as 0.5% Wescodyne™ Plus), or a phenolic, etc.) and wiped dry.

Spills containing acid should be appropriately absorbed (wiped up) or neutralized, wiped dry and then the area wiped with one of the chemical disinfectants; material used to absorb the spill may require biohazardous waste disposal.

NOTE: DO NOT PLACE SOLUTIONS CONTAINING BLEACH INTO THE AUTOCLAVE.

6 - PRECAUTIONS FOR USERS

Safety Precautions:

1. This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Handle appropriately with the requisite Good Laboratory Practices. Wear appropriate protective clothing, including lab coat, eye/face protection and

disposable gloves (synthetic, non-latex gloves are recommended) while handling kit reagents and patient samples. Wash hands thoroughly after performing the test.

2. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
3. Do not pipette by mouth.
4. **This Product Contains Dry Natural Rubber in the dropper bulb used with the Specimen Diluent bottle.**
5. **Dispose of all specimens and materials used to perform the test as biohazardous waste. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations. For additional information on biosafety requirements, refer to CDC recommendations for Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens.¹**
6. Complete hazard information and precautions are located in the Safety Data Sheet (SDS) available at bio-rad.com or upon request.

Handling precautions:

1. Do not use any kit components beyond their stated expiration date.
2. Do not mix components from different lots.
3. Do not use the components in any other type of test kit as a substitute for the components in this test kit.
4. Use the Multispot HIV-1/HIV-2 Cartridge and disposable Transfer Pipets only once and then dispose of as described in Safety Precautions. Do not reuse these kit components.
5. Exercise care in opening and reusing reagent bottles to avoid microbial contamination of the reagents.
6. Prior to running the assay, verify that the prefilter is seated firmly on top of the Cartridge by pressing down firmly and evenly.
7. Always hold each reagent bottle vertically and allow each reagent to fall freely from the dropper tip. Do not touch the dropper tip to any surface; this may contaminate the reagent.
8. Avoid contact of the Stop Solution with any oxidizing agent. Do not allow Stop Solution to come into contact with metals.
9. Handle the Negative and Positive Control Serums in the same manner as patient specimens.
10. Inadequate adherence to package insert instructions may result in erroneous results.
11. When removing the Transfer Pipets from the bag, avoid touching the tips of the pipets.
12. The test should be performed with Cartridges that are placed on a flat surface.
13. Adequate lighting is required to read test results.

7 - REAGENT PREPARATION AND STORAGE

All solutions and reagents are ready to use as supplied. Store kit at 2-8°C or room temperature (20-30°C). If stored at 2-8°C, bring all reagents to room temperature before use, and return entire kit to 2-8°C when not in use. The kit may be used up to kit expiration when stored at 2-8°C or for up to 3 months if stored at room temperature. When stored at room temperature, change the expiration date to three months after start of room temperature storage (do not change the date if less than 3 months expiration remains on the kit). Do not freeze test components.

8 - SPECIMEN COLLECTION, PREPARATION, AND STORAGE

Fresh or frozen serum or plasma collected by standard phlebotomy procedures may be used in the test. The minimally acceptable volume of specimen available for performing the test is 40 µL. Approximately 30 µL is used for running each test. No clinically significant effect has been detected in assay results of serum or plasma samples with increased levels of hemoglobin, protein, albumin, lipids, or bilirubin. **Performance of this assay has not been evaluated on patient samples that have been heat-inactivated.**

The following anticoagulants have been evaluated and found to be acceptable for use with this test: EDTA, sodium citrate, sodium heparin, and SST tubes. Samples that are collected into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution. **Use of other anticoagulants has not been evaluated and may give incorrect results.**

Specimens may be stored at 2-8°C for 7 days or at room temperature (20-30°C) for up to 48 hours. For long-term storage, the specimens should be frozen (-20°C or colder). Specimens may be frozen and thawed up to 5 times.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

9 - MULTISPOT HIV-1/HIV-2 RAPID TEST PROCEDURE

Materials Provided

See REAGENTS section on page 5.

Additional Materials Provided which are included in the kit:

- Package insert (1)
- Subject Information Notice (1) - The Notice in the kit box may be copied as needed.
- Customer letter (1)

Materials Required But Not Provided

1. Disposable glass or polypropylene test tubes (do not use polystyrene) to prepare diluted specimens and controls (for example: 12 x 75 mm tubes)
2. Test tube racks
3. Absorbent pads or paper towels
4. Biohazard bags with closures
5. Household bleach (5% or 8% sodium hypochlorite), diluted to a minimum concentration of 10% bleach (0.5% sodium hypochlorite). Alternative disinfectants include 70% ethanol or 0.5% Wescodyne™.
6. Disposable gloves.
7. Laboratory timer.
8. Precision pipettors that deliver 30 µL and 300 µL (optional for addition of specimen and Specimen Diluent). Precision pipettors that deliver 10 µL and 90 µL as needed for dilutional testing of dually positive samples.
9. Indelible laboratory marker.

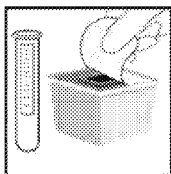
Preliminary Statements

1. **Once testing has been started, it should be completed without interruption.**
2. Do not use more than ten (10) Multispot HIV-1/HIV-2 Cartridges in a batch, since using more Cartridges may make it difficult to complete the testing without interruption. Larger numbers of specimens can be tested by running several batches of up to 10 Cartridges.
3. The eyedropper used to dispense Specimen Diluent is packaged separately from the bottle of Specimen Diluent. The first time a kit is used, remove the eyedropper from the packaging and insert it into the bottle of Specimen Diluent. Discard the original cap and use the eyedropper as the cap for the bottle. Two full eyedroppers dispenses approximately 300 µL of Specimen Diluent.
4. A 30µL precision pipettor can be used for addition of the sample to the Specimen Diluent. The disposable Transfer Pipets supplied in the kit dispense approximately 30 µL per drop.
5. The Cartridges should be placed on a flat surface during the assay procedure to ensure proper flow of specimen and reagents through the membrane.
6. **All solutions must be completely absorbed (no standing liquid) into the Cartridge membrane before proceeding to the next step in the Assay Procedure.**

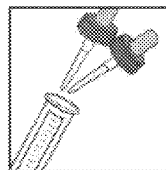
Assay Procedure

1. **Bring kit and specimens to room temperature (20-30°C) before beginning testing. It is essential that all kit components are at room temperature before use.**
2. **Place the required number of Cartridges on a flat surface with the patient ID label facing toward the operator.** Peel away the foil seals and discard them. Label the Cartridges to correspond with the test tubes and the specimens to be tested.
Note: Verify that the blue prefilter and gray top support are seated securely in the base of the Cartridge by pressing down firmly and evenly on both pieces. The prefilter must be present in order to use the Cartridge for testing.
3. **Label a test tube for each specimen or control to be tested.**
4. **Invert the Specimen Diluent bottle ten times to thoroughly mix just prior to drawing the reagent.**
5. **Add two full eyedroppers of Specimen Diluent to each specimen and control tube.**
Note: With the eyedropper in the Specimen Diluent, hold vertically and squeeze the bulb completely, draw Specimen Diluent up into the eyedropper, and gently expel all of the Specimen Diluent into the test tube. Repeat this sequence to deliver the second full eyedropper.
6. Using a precision pipet with a separate pipet tip for each sample, add 30µL of specimen to the Specimen Diluent. Alternatively, using a separate Transfer Pipet for each specimen, draw up a small amount of specimen. **While holding the pipet vertically over the appropriate dilution tube, add one drop to the tube. Note:** *The drop should fall freely into the Specimen Diluent, not onto the side of the tube. If the drop does fall onto the side of the tube, make sure that the entire drop drains down into the Specimen Diluent. If the drop does not drain into the Specimen Diluent, discard the tube and prepare a new dilution.* Do not allow the tip of the pipet to touch any part of the tube or the Specimen Diluent in the tube. Discard the used pipet tip or Transfer Pipet into the biohazardous waste.
7. Test Positive and Negative Control Serums as described in the QC section. When preparing Positive and Negative Control Serums, hold the dropper bottles **vertically** over the tubes labeled for controls and squeeze gently.
Add one drop of each control to the appropriately labeled tube. The drop should fall freely into the Specimen Diluent (see Note in Step 6 above). Do not allow the tip of the dropper to touch any part of the tube.
8. **Mix each diluted specimen and control (when run) thoroughly. Mix gently to avoid foaming.**
9. **Pour the contents of each tube into the specimen prefilter of each corresponding pre-labeled Cartridge, using a separate Cartridge for each tube. Wait two minutes, after which the solution must be completely absorbed through the prefilter into the Cartridge.**
10. **Remove and discard the prefilter into the biohazardous waste.**
11. **Fill the central well of each Cartridge with Wash Solution by holding the bottle vertically and squeezing gently.** Do not touch bottle to solution in Cartridge well. ***Wait for the Wash Solution to be absorbed completely before proceeding.***
12. **Add three drops of Conjugate to the central well of each Cartridge by holding the bottle vertically and squeezing gently.** Do not touch bottle tip to solution in Cartridge well. ***Wait two minutes.***
13. **Fill the central well of each Cartridge with Wash Solution by holding the bottle vertically and squeezing gently.** Do not touch bottle to solution in Cartridge well. ***Wait for the Wash Solution to be fully absorbed before proceeding.***
14. **Repeat step 13 so that each Cartridge is washed twice. *Wait for the Wash Solution to be absorbed completely before proceeding.***
15. **Add three drops of Development Reagent to the central well of each Cartridge by holding the bottle vertically and squeezing gently. *Wait five minutes.***

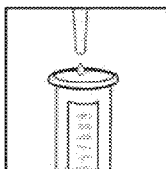
16. **Fill the central well of each Cartridge with Stop Solution** by holding the bottle vertically and squeezing gently. ***Wait for the Stop Solution to be absorbed completely before reading results.***
17. Read test results according to Test Result Appearance and Interpretation, Section 11 (Rapid Testing) or Section 14 (Antibody Differentiation Test in a Diagnostic Testing Algorithm), either immediately or anytime up to 4 hours after completing the test. An elevated background can appear over time with some specimens; therefore, reading results within 1 hour is optimal.



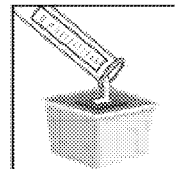
1. Remove foil; press prefilter down. Label cartridge and specimen or control test tubes.



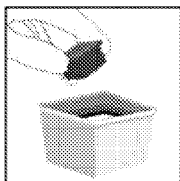
2. Add 2 full droppers of Specimen Diluent to each test tube.



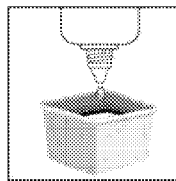
3. Add one drop of each sample or control to each labeled tube using a transfer pipette. Mix well.



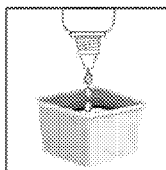
4. Pour each sample into the prefilter of the labeled cartridge. Wait 2 minutes.



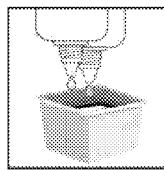
5. Remove and discard prefilter.



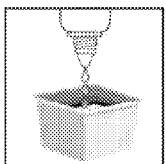
6. Fill the central well of each cartridge with Wash Solution.



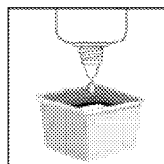
7. Once absorbed, add 3 drops of Conjugate. Wait 2 minutes.



8. Fill well with Wash Solution and let absorb. Repeat.



9. Add 3 drops of Development Reagent. Wait 5 minutes.



10. Fill well with Stop Solution. Allow to absorb and read results.

10 - QUALITY CONTROL – VALIDATION OF RESULTS

Procedural Control

Each Multispot HIV-1/HIV-2 Cartridge has a built-in procedural control, the Procedural Control Spot, which is used to determine validity of the assay. The Procedural Control Spot must be reactive (a definite purple spot) on each Cartridge for the results of that Cartridge to be valid.

Quality Control

Using individual Multispot HIV-1/HIV-2 Cartridges as described in the Assay Procedure above, run 1 Positive Control Serum and 1 Negative Control Serum (both provided in the kit) under the following circumstances to monitor proper test performance:

- A new operator uses the kit, prior to performing testing of specimens.
- A new test kit lot is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit falls outside of 2-30°C (35.6-86°F).
- The temperature of the test area falls outside of 20-30°C (68-86°F).
- According to intervals defined by the testing facility.

Results are read by examining the membrane and comparing the location of colored spots on the membrane to the diagram below. **Position the Multispot HIV-1/HIV-2 Cartridge with the ID label facing the user.** The appearance of any purple color in any of the Test Spots, regardless of intensity, must be considered as presence of that Spot.

Expected results are as follows:



Negative Control

Only the Procedural Control Spot shows purple color development. The 3 Test Spots show no color development.

← Note placement of Cartridge ID label.



Positive Control

The Procedural Control Spot, both HIV-1 Test Spots, and the HIV-2 Test Spot show purple color development.

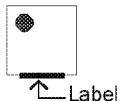
11 - TEST RESULT APPEARANCE AND INTERPRETATION – RAPID HIV-1/HIV-2 TESTING

Note: For interpretation of the assay when used as the differentiation assay in a diagnostic testing algorithm, refer to Section 14 - USE OF MULTISPOT AS THE ANTIBODY DIFFERENTIATION TEST IN A DIAGNOSTIC TESTING ALGORITHM

Place the Cartridges with the patient ID label facing toward the operator prior to reading test results. Examine the Cartridge membrane and compare the location of colored spots to the diagram below. The appearance of any purple color must be considered as presence of that Spot. Follow the CDC guidelines for counseling, testing, and referral when informing test subjects of these HIV test results and their interpretation.⁴²

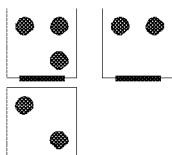
Interpretation for Rapid HIV-1/HIV-2 Testing:

Nonreactive - Report results as described in the CDC guidance for reporting test results and interpretation.⁴²



Only the Procedural Control Spot shows purple color development. The 3 Test Spots show no color development. Test result is interpreted as negative for HIV-1 and HIV-2 antibodies.

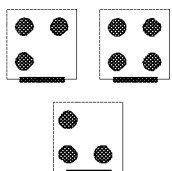
Reactive (Preliminary Positive) - Report results as described in the CDC guidance for reporting test results and interpretation.⁴²

**HIV-1 Reactive - Preliminary Positive:**

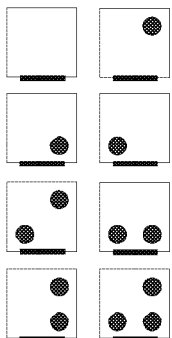
The Procedural Control Spot shows purple color development and the recombinant HIV-1 Spot and/or the HIV-1 Peptide Spot show purple color development. Test result is interpreted as Preliminary Positive for HIV-1 antibodies.

**HIV-2 Reactive - Preliminary Positive:**

The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development. Test result is interpreted as Preliminary Positive for HIV-2 antibodies.

**HIV Reactive (Undifferentiated) - Preliminary Positive:**

The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development as well as one or both HIV-1 Spots. In this case, the specimen may be tested by additional methods which allow for differentiation between HIV-1 and HIV-2. See dilutional procedure which follows.

Invalid - Do not report any results

If no color develops in the Procedural Control Spot, regardless of color development anywhere else on the membrane, the results are **INVALID**. (See examples.)

If the background on the membrane is dark and interferes with the interpretation of the spots, the results are invalid. In addition, if there are stray purple marks or discoloration that interfere with reading the spots, the assay should be repeated. Repeat the assay, and if results are still invalid collect a fresh sample or test by another method.

Note: The appearance of any purple color in any of the Test Spots, regardless of intensity, must be considered as presence of that Spot.

Dilutional Procedure for HIV Differentiation – Rapid HIV-1/HIV-2 Testing

The following procedure is used to differentiate samples that demonstrate purple color development in the HIV-2 Spot as well as in one or both of the HIV-1 Spots.

1. Dilute the specimen 1:10 (using a calibrated pipettor, add 90 μ L of Negative Control Serum and 10 μ L of sample to a separate test tube; or, alternatively, 135 μ L of Negative Control Serum and 15 μ L of sample). Mix well.
2. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:10 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
3. Read the results according to the criteria above in Test Result Appearance and Interpretation.
 - If the results are nonreactive at this dilution, the specimen should be interpreted as **“Preliminary Positive for antibodies to HIV (undifferentiated).”**

- If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as Preliminary Positive for antibodies to the specific HIV type identified.
 - If one or both of the HIV-1 Spots and the HIV-2 Spot are still reactive, continue testing as follows.
4. Dilute the 1:10 diluted specimen again by 10-fold in Negative Control Serum, following the procedure in step 1 above (the final dilution is 1:100).
 5. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:100 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
 6. Read the results according to the criteria above in Test Result Appearance and Interpretation.
 - If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as Preliminary Positive for antibodies to the specific HIV type identified.
 - If the dual HIV reactivity does not disappear at the 1:100 dilution, or if the HIV-1 and HIV-2 spots both become nonreactive at the same dilution, the specimen should be interpreted as **“Preliminary Positive for antibodies to HIV (undifferentiated).”**

Follow CDC guidelines for counseling, testing, and referral when informing test subjects of these HIV test results and their interpretation.⁴²

12. LIMITATIONS OF THE PROCEDURE

1. For a preliminary positive result, when used as a rapid HIV-1/HIV-2 test, clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing (for example, Western blot or indirect immunofluorescence assay) to decide whether a diagnosis of HIV infection is accurate.
2. The Assay Procedure and the Test Result Appearance and Interpretation must be followed closely when testing for the presence of antibodies to HIV-1 or HIV-2 in plasma or serum from individual subjects. Failure to follow the procedure may give inaccurate results.
3. The test was designed to test individual specimens of fresh or frozen serum or plasma. Data regarding test kit interpretation were derived from testing individual samples. Insufficient data are available to interpret tests performed on other body specimens, pooled blood or processed plasma, and products made from such pools. Testing of these specimens is not recommended.
4. The following anticoagulants have been evaluated and found to be acceptable for use with this test: EDTA, sodium citrate, sodium heparin and SST tubes. **Use of other anticoagulants has not been evaluated and may give incorrect results.**
5. Performance of this assay has not been evaluated on patient samples that have been heat-inactivated.
6. Polystyrene tubes should not be used to prepare specimens for this test.
7. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. Testing alone cannot be used to diagnose AIDS, even if the recommended investigation of reactive specimens suggests a high probability that the antibody to HIV-1 or HIV-2 is present.
8. A nonreactive result for an individual subject indicates absence of detectable HIV antibodies. However, a nonreactive test result does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2.
9. Nonreactive results can occur if the quantity of marker present in the sample is below the detection limits of the assay, or if the marker that is detected is not present during the stage of disease in which a sample is collected.
10. The risk of any asymptomatic person with a reactive serum or plasma developing AIDS or an AIDS-related condition is not known, as the course of HIV infections may vary among individual patients and may be altered by antiretroviral therapy. However, in a prospective study, AIDS developed in 51% of homosexual men after 10 years of infection.⁴³
11. A person who has antibodies to HIV-1 is presumed to be infected with the virus, except a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.

12. Specimens which are reactive for antibodies to both HIV-1 and HIV-2 on initial testing should be retested, according to the dilutional test protocol, to identify potential cross-reaction and differentiate between HIV-1 and HIV-2. Results of dilutional testing, when used for rapid HIV-1/HIV-2 testing, should be reported as Preliminary Positive for antibodies to the specific virus type identified in the dilutional testing. Specimens that are dually reactive when tested undiluted but only reactive for one virus type at the 1:100 dilution may be dually positive; these samples are reported as Preliminary Positive for antibodies to the specific HIV type identified, when used for rapid HIV-1/HIV-2 testing.
13. The intensity of the Test Spot does not correlate with antibody titer of the specimen.
14. Samples reactive for both HIV-1 and HIV-2 may resolve to HIV-1 at higher dilutions due to the lower avidity of the HIV-2 antibody as compared to the HIV-1 antibody.
15. **The Multispot HIV-1/HIV-2 Rapid Test cannot be used as part of a diagnostic testing algorithm for both the initial testing and the differentiation testing of the same sample.**

13. EXPECTED PERFORMANCE CHARACTERISTICS – RAPID HIV-1/HIV-2 TESTING

Sensitivity for Antibodies to HIV-1

Sera

The reactivity of the Multispot HIV-1/HIV-2 Rapid Test was evaluated at two geographically diverse locations in the U.S. with 801 fresh serum samples from known HIV-1-positive individuals, and at three geographically diverse locations in the U.S. with 620 prospective fresh sera from patients at high risk for HIV-1 infection. The results of testing with the Multispot HIV-1/HIV-2 Rapid Test, a licensed EIA, and Western blot are shown below in Table 1.

Table 1 - Detection of HIV-1 Antibody in Serum Samples

Population	# of Samples Tested	Multispot Reactive	Licensed HIV-1 EIA Repeatedly Reactive	Licensed HIV-1 Western Blot Positive
HIV-1 Known Positive, U.S. Fresh Sera	801	801	801	801
HIV-1 High-Risk Fresh Sera	620	28	29 ^a	28
Total	1421	829	830	829

^a One specimen was Negative on HIV-1 Western blot.

Of the 829 confirmed HIV-1-positive serum samples from known HIV-1 positive individuals and from individuals at high risk for HIV-1 infection, all 829 were reactive when tested on the Multispot HIV-1/HIV-2 Rapid Test. Based on these studies, the sensitivity of the Multispot HIV-1/HIV-2 Rapid Test for antibodies to HIV-1 with serum specimens is calculated to be 100% (95% CI = 99.94 – 100.00%).

Plasma

The reactivity of the Multispot HIV-1/HIV-2 Rapid Test was evaluated at two geographically diverse locations in the U.S. with 801 fresh plasma samples from known HIV-1 positive individuals, and at four geographically diverse locations in the U.S. with 1441 prospective fresh plasma from patients at high risk for HIV-1 infection. The results of testing with the Multispot HIV-1/HIV-2 Rapid Test, a licensed EIA, and Western blot are shown below in Table 2.

Table 2 - Detection of HIV-1 Antibody in Plasma Samples

Population	# of Samples Tested	Multispot Reactive	Licensed HIV-1 EIA Repeatedly Reactive	Licensed HIV-1 Western Blot Positive
HIV-1 Known Positive, U.S. Fresh Plasma	801	801	801	801
HIV-1 High-Risk Fresh Plasma	1441	70	72 ^a	70
Total	2242	871	873	871

^a One specimen was Indeterminate and one specimen was Negative on HIV-1 Western blot.

Of the 871 confirmed HIV-1 positive plasma samples from known HIV-1 positive individuals and from individuals at high risk for HIV-1 infection, all 871 were reactive when tested on the Multispot HIV-1/HIV-2 Rapid Test. Based on these studies, the sensitivity of the Multispot HIV-1/HIV-2 Rapid Test for antibodies to HIV-1 with plasma specimens is calculated to be 100% (95% CI = 99.94 – 100.00%).

Sensitivity for Antibodies to HIV-2

The ability of the Multispot HIV-1/HIV-2 Rapid Test to detect antibodies to HIV-2 in samples known to be positive for HIV-2 is presented in Table 3. Samples were frozen sera (N=61) and frozen plasma (N=140) and were collected in Africa (N=163), the United States (N=13) and unknown locations (N=25). All samples tested were positive on a research use HIV-2 Western blot, and repeatedly reactive on both a licensed HIV-2 EIA and on a licensed HIV-1/HIV-2 EIA. In addition, the ability of Multispot HIV-1/HIV-2 to detect HIV-2 antibodies in specimens collected prospectively from individuals in an HIV-2 endemic area was evaluated on 500 frozen serum specimens previously collected in Sierra Leone, Africa.

Table 3 - Detection of HIV-2 Antibody in Serum/Plasma Samples

Population	# of Samples Tested	HIV-2 Western Blot (Research Use) Positive	
		Multispot Reactive	Licensed HIV-2 EIA and HIV-1/HIV-2 EIA Repeatedly Reactive
HIV-2 Known Positive	201	201 ^a	201
HIV-2 Endemic Population	500	6 ^b	6 ^b
Total	701	207	207

^a Two specimens were identified as positive for both HIV-1 and HIV-2 based on results of Western blot and PCR testing.

^b Western blot testing identified 2 of these specimens as positive for both HIV-1 and HIV-2.

As shown in Table 3, of the 207 confirmed HIV-2 positive specimens (i.e., HIV-2 Western blot positive) from known HIV-2 positive individuals and from individuals in an HIV-2 endemic population, all 207 were reactive when tested on the Multispot HIV-1/HIV-2 Rapid Test. Based on the results from these studies, the sensitivity of the Multispot HIV-1/HIV-2 Rapid Test for antibodies to HIV-2 is calculated to be 100% (95% CI = 99.76 – 100%).

HIV-1 and HIV-2 Differentiation

The ability of Multispot to differentiate HIV-1 and HIV-2 antibodies was determined by evaluating the samples that were identified by Western blot testing as positive for HIV-1 or HIV-2, as shown below in Table 4.

Table 4 - Differentiation of HIV-1 and HIV-2 Antibodies in Western Blot Positive Samples

HIV Status ^a	Number of Specimens	Multispot Test Result Interpretation ^b			% Correct
		HIV-1	HIV-2	HIV-1/HIV-2	
HIV-1	1071	1070	0	1	99.91%
HIV-2	109	0	107	2	98.16%

^a HIV-1 status was determined based on a positive result on a licensed HIV-1 Western blot. HIV-2 status was determined based on a positive result on a research use HIV-2 Western blot, with a corresponding negative or indeterminate result on a licensed HIV-1 Western blot.

^b Interpretation was based on initial Multispot test results if reactive for HIV-1 or HIV-2 only, or on the result from testing of diluted specimens that were reactive for both HIV-1 and HIV-2 on initial test results.

HIV-1:

In the HIV-1 known positive and high-risk populations, there were 1071 samples that were HIV-1 positive by Western blot (1001 from known positive U.S. and worldwide populations and 70 from high risk populations). Multispot identified 1070 of the 1071 samples as HIV-1 reactive only (1070/1071 = 99.91%; 95% CI of 99.68 – 100.00%). The remaining sample, which was HIV-2 Western blot indeterminate, was dually reactive (undifferentiated) on Multispot HIV-1/HIV-2.

Of the 801 samples from known HIV-1 positive U.S. individuals, all were positive by HIV-1 Western blot and all were reactive with the Multispot HIV-1/HIV-2 Rapid Test. Seven hundred ninety-nine (799) of the 801 samples (99.8%) were detected as HIV-1 reactive only on Multispot HIV-1/HIV-2, and the remaining 2 samples were dually reactive (undifferentiated) on Multispot HIV-1/HIV-2. Multispot identified 799 of the 801 known HIV-1 positive samples as HIV-1 reactive only ($799/801 = 99.75\%$; 95% CI of 99.34 – 100.00%).

HIV-2:

In the known HIV-2 positive population, there were 109 samples that were HIV-2 positive only by Western blot, and 92 samples were also positive by HIV-1 Western blot. Multispot identified 107 of these 109 samples as reactive for HIV-2 only ($107/109 = 98.16\%$; 95% CI of 95.14 – 100.00%). The 2 remaining samples, which were indeterminate on HIV-1 Western blot, were dually reactive (undifferentiated) on Multispot.

Of the 201 samples from known HIV-2 positive individuals, all were positive by HIV-2 Western blot and all were reactive with the Multispot HIV-1/HIV-2 Rapid Test. One hundred ninety (190) of these 201 known HIV-2 specimens (94.5%) were detected as HIV-2 reactive only on Multispot HIV-1/HIV-2. Nine were reactive for both HIV-1 and HIV-2 and two were identified by Multispot as HIV-1 reactive. Note: Samples reactive for both HIV-1 and HIV-2 may resolve to HIV-1 due to the lower titer of the HIV-2 antibody as compared to the HIV-1 antibody. Dual infections with both HIV-1 and HIV-2 viruses are unusual but may occur in individuals from HIV-2 endemic countries.⁴⁴

Reactivity of Multispot HIV-1/HIV-2 on Worldwide Specimens and on HIV-1 Group O Serotype Samples

A total of 79 frozen serum and 124 frozen plasma specimens from various worldwide geographic locations outside of the U.S. were tested on Multispot HIV-1/HIV-2. HIV-1 subtypes represented included subtypes A, B, C, D, E, F, and G. All 203 specimens from this worldwide panel were reactive on Multispot HIV-1/HIV-2. In addition, 12 HIV-1 Serotype Group O frozen plasma samples were tested on Multispot HIV-1/HIV-2. Ten (10) samples were from Cameroon, one was from Spain, and one was from the United States. Eleven (11) of the 12 HIV-1 Group O serotype samples were reactive when tested on Multispot HIV-1/HIV-2, and one was nonreactive.

Reactivity with Seroconversion and Sensitivity (Low and Mixed Titer) Panels

Sensitivity was also assessed by testing 10 commercial seroconversion panels and 3 low/mixed titer sensitivity panels. The results of seroconversion panel testing, in comparison to results with a licensed HIV-1/HIV-2 EIA and a licensed HIV-1 Western Blot, are shown in Table 5. Multispot HIV-1/HIV-2 detected the presence of antibody to HIV-1 in specimens from ten Seroconversion Panels as early as, or earlier than, a licensed HIV-1/HIV-2 EIA.

Table 5 - HIV-1 Seroconversion Panels, N=10

Panel ID		Day Since 1st Bleed	Multispot Result	Licensed HIV-1/HIV-2 EIA
L	PRB912-01	0	Negative	NR
	PRB912-02	9	HIV-1	RR
	PRB912-03	14	HIV-1	RR
V	PRB922-01	0	Negative	NR
	PRB922-02	4	HIV-1	NR
	PRB922-03	7	HIV-1	RR
	PRB922-04	11	HIV-1	RR
AB	PRB927-01	0	Negative	NR
	PRB927-02	28	Negative	NR
	PRB927-03	33	HIV-1	R
	PRB927-04	35	HIV-1	R
	PRB927-05	40	HIV-1	R
AD	PRB929-01	0	Negative	NR
	PRB929-05	21	Negative	NR
	PRB929-06	25	Negative	NR
	PRB929-07	28	HIV-1	R
AI	PRB934-01	0	Negative	NR
	PRB934-02	7	HIV-1	RR
	PRB934-03	11	HIV-1	RR
AP	PRB940-01	0	Negative	NR
	PRB940-03	11	Negative	NR
	PRB940-04	15	HIV-1	RR
	PRB940-05	18	HIV-1	RR
	PRB940-06	22	HIV-1	RR
	PRB940-07	25	HIV-1	RR
	PRB940-08	29	HIV-1 & HIV-2	RR
AQ	PRB941-01	0	Negative	NR
	PRB941-03	9	Negative	NR
	PRB941-04	18	HIV-1	NR
	PRB941-05	21	HIV-1	NR
	PRB941-06	25	HIV-1	RR
AT	PRB944-01	0	Negative	NR
	PRB944-04	9	Negative	NR
	PRB944-05	14	HIV-1	R
	PRB944-06	16	HIV-1	R
AU	PRB945-01	0	Negative	NR
	PRB945-04	13	Negative	NR
	PRB945-05	15	Negative	NR
	PRB945-06	20	HIV-1	R
SV	SV-0401-A	0	Negative	NR
	SV-0401-E	14	Negative	NR
	SV-0401-F	18	HIV-1	RR
	SV-0401-G	22	HIV-1	RR

NR = Nonreactive, RR = Repeatedly Reactive, R = Reactive (single test)

The results of testing Multispot HIV-1/HIV-2 on 2 low titer panels and 1 mixed titer panel, in comparison to a licensed HIV-1/HIV-2 EIA, are shown in Tables 6 and 7. Multispot HIV-1/HIV-2 was able to detect antibodies to HIV-1 similar to the licensed EIA.

Table 6 - HIV-1 Low Titer Panels

	Panel ID	Multispot Result	Licensed HIV-1/HIV-2 EIA
PRB106	01	HIV-1	R
	02	Negative	R
	03	HIV-1	R
	04	HIV-1	R
	05	HIV-1	R
	06	Negative	NR
	07	HIV-1	R
	08	HIV-1	NR
	09	HIV-1	R
	10	HIV-1	R
	11	HIV-1	R
	12	HIV-1	R
	13	HIV-1	R
	14	HIV-1	R
	15	HIV-1	R
PRB107	01	Negative	NR
	02	HIV-1	NR
	03	HIV-1	NR
	04	HIV-1	R
	05	Negative	NR
	06	HIV-1	R
	07	HIV-1	NR
	08	Negative	R
	09	Negative	NR
	10	HIV-1	R
	11	HIV-1	R
	12	Negative	NR
	13	Negative	NR
	14	HIV-1	R
	15	HIV-1	R

NR = Nonreactive, R = Reactive (single test)

Table 7 - HIV-1 Mixed Titer Panel (PRB203)

Panel ID	Multispot Result	Licensed HIV-1/HIV-2 EIA
PRB203-01	HIV-1	RR
PRB203-02	HIV-1	RR
PRB203-03	Negative	NR
PRB203-04	HIV-1	NR
PRB203-05	HIV-1	RR
PRB203-06	HIV-1	RR
PRB203-07	HIV-1	RR
PRB203-08	HIV-1	RR
PRB203-09	HIV-1	RR
PRB203-10	HIV-1	RR
PRB203-11	HIV-1	RR
PRB203-12	HIV-1	RR
PRB203-13	HIV-1	RR
PRB203-14	HIV-1	NR
PRB203-15	HIV-1	RR
PRB203-16	HIV-1	RR
PRB203-17	HIV-1	RR
PRB203-18	HIV-1	RR
PRB203-19	HIV-1	RR
PRB203-20	Negative	NR
PRB203-21	HIV-1	RR
PRB203-22	HIV-1	NR
PRB203-23	HIV-1	RR
PRB203-24	HIV-1	RR
PRB203-25	HIV-1	RR

NR = Nonreactive, RR = Repeatedly Reactive

Specificity**Sera**

The specificity of Multispot HIV-1/HIV-2 with serum samples was evaluated in both low and high-risk populations for HIV infection. Samples in the three low-risk populations were obtained from a regional blood donor center (N=505) and from 2 low prevalence areas (N=200 and N=199) in geographically distinct areas of the United States. One specimen from the low risk population was confirmed positive for HIV infection and was excluded from the specificity analysis, giving a total of 903 specimens. An additional 592 HIV antibody-negative samples collected from individuals of unknown HIV serostatus in the population of 620 individuals at high risk for HIV described above in the Sensitivity section (Table 1) were added to the low risk population for calculation of total specificity for serum specimens. These added 592 samples were from 3 clinical sites and were nonreactive by HIV-1 EIA and negative by HIV-1 Western blot. The results of testing using Multispot HIV-1/HIV-2 compared to results with the reference test are shown in Table 8.

Table 8 - Specificity in Low and High-Risk Populations Fresh Sera

Test Group	Total Samples Negative by Reference Test ^a	Multispot Reactive	Multispot Nonreactive
Low Risk	903	1	902
High Risk	592	0	592
Totals	1495	1	1494

^a Includes all samples nonreactive by HIV-1 EIA and those reactive by HIV-1 EIA that were negative on HIV-1 Western blot

Of the 1495 samples from individuals at low risk and high risk for HIV infection that were negative for antibodies to HIV by reference testing, 1494 were nonreactive on Multispot HIV-1/HIV-2. One (1) serum sample that was reactive for HIV-1 on Multispot was nonreactive on HIV-1/HIV-2 EIA and HIV-2 EIA, and negative by HIV-1 Western blot.

Combining the data from the studies of low-risk fresh serum samples and the high-risk fresh serum samples that were negative for antibodies to HIV by the reference test, the specificity of the Multispot HIV-1/HIV-2 Rapid Test using serum specimens in these studies is calculated to be 1494/1495 or 99.93% (95% CI = 99.79 – 100.00%).

Plasma

The specificity of Multispot HIV-1/HIV-2 with plasma samples was evaluated in both low and high-risk populations for HIV infection. Samples were obtained from a regional blood donor center (N=505) and from 2 low prevalence areas (N=200 plasma and N=199 plasma) in geographically distinct areas of the United States. One specimen from the low-risk population was confirmed positive for HIV infection and was excluded from the specificity analysis, giving a total of 903 specimens. An additional 1371 HIV-1 antibody-negative fresh plasma samples collected from individuals of unknown HIV serostatus in a population at high risk for HIV (taken from the high-risk population described in the Sensitivity section above, Table 2) were added to the low-risk population for calculation of total specificity for plasma specimens, as shown in Table 9.

Table 9 - Specificity in Low and High-Risk Populations Fresh Plasma

Test Group	Total Samples Negative by Reference Test ^a	Multispot Reactive	Multispot Nonreactive
Low Risk	903	2	901
High Risk	1371	0	1371
Totals	2274	2	2272

^a Includes all samples nonreactive by HIV-1 EIA and those reactive by HIV-1 EIA that were negative on HIV-1 Western blot

Of the 2274 samples from individuals at low risk and high risk for HIV infection that were negative for antibodies to HIV by reference testing, 2272 were nonreactive on Multispot HIV-1/HIV-2. Two (2) plasma samples that were reactive for HIV-1 on Multispot were nonreactive on HIV-1/HIV-2 EIA or HIV-2 EIA, and negative by HIV-1 Western blot.

Combining the data from the studies of low-risk fresh plasma samples and the high-risk fresh plasma samples that were negative for antibodies to HIV by the reference test, the specificity of the Multispot HIV-1/HIV-2 Rapid Test using plasma specimens in these studies is calculated to be 2272/2274 or 99.91% (95% CI = 99.77 – 100.00%).

Interfering Substances and Unrelated Medical Conditions

The Multispot HIV-1/HIV-2 Rapid Test was evaluated in studies of samples with potentially interfering substances, with various anticoagulants, and from individuals with unrelated medical conditions to determine any effect on test sensitivity and specificity.

Potentially interfering substances and anticoagulants tested, and the number of specimens tested, are as follows: hemolyzed (20), icteric (20), lipemic (20), elevated albumin (20), SST serum (10), EDTA plasma (10), heparin plasma (10), and citrated plasma (10). The sensitivity and specificity of Multispot was not affected by the presence of these interfering substances or anticoagulants, with the exception of one icteric specimen whose test results were uninterpretable on repeated testing due to high background.

Performance of Multispot HIV-1/HIV-2 was evaluated on a series of 227 unspiked specimens from individuals with unrelated medical conditions. In addition, two aliquots of each specimen were spiked

with an HIV-1 or an HIV-2 positive specimen to give a level of reactivity in the low positive range. Results from the testing of these unspiked and HIV-1 and HIV-2 spiked specimens are shown in Table 10.

Table 10 - Unrelated Medical Conditions

Unrelated Medical Condition	Unspiked Aliquots with Negative Results	HIV-1 Spiked Aliquots with HIV-1 Results	HIV-2 Spiked Aliquots with HIV-2 Results
Anti-HAV	12/12	10/10	10/10
Anti-HCV	12/12	10/10	10/10
Anti-EBV	12/12	10/10	10/10
Anti-HSV	12/12	10/10	9/10 ^e
Anti-CMV	14/14	10/10	10/10
Anti-HTLV-I	9/10 ^a	10/10	10/10 ^f
Anti-HTLV-II	11/12 ^b	9/10 ^c	9/10 ^c
Anti-Rubella	12/12	10/10	10/10
Anti-Toxoplasmosis	11/12 ^b	10/10	10/10
Cancers	10/10	9/10 ^c	10/10
Cirrhosis	10/10	10/10	10/10
Elevated IgG	10/10	9/10 ^c	9/9
Elevated IgM	10/10	10/10	10/10
HBsAg +	15/15	10/10	10/10 ^f
Rheumatoid Factor +	10/10	10/10	10/10
RPR +	10/10	8/10 ^d	10/10
Multiparous	12/12	10/10	10/10
Multi-Transfused	12/12	10/10	10/10
Systemic Lupus	9/10 ^b	10/10	10/10
VZV+	10/10	10/10	9/10 ^c
TOTALS	223/227 (98.2%)	195/200 (97.5%)	196/199 (98.5%)

^a One un-spiked sample in this group was falsely reactive for HIV-2.

^b One un-spiked sample in this group was falsely reactive for HIV-1.

^c One spiked sample in this group was falsely nonreactive.

^d Two spiked samples in this group were falsely nonreactive.

^e One sample in this group spiked with HIV-2 was HIV-1 reactive.

^f One sample in this group, spiked with HIV-2, was dually reactive for HIV-1 and HIV-2.

Overall, in the 227 unrelated medical condition (UMC) samples, 223 were nonreactive in Multispot. Falsely reactive results were observed in 1 sample each from specimens containing antibodies to HTLV-I, HTLV-II, toxoplasmosis, and SLE. Of the 200 UMC samples spiked with low levels of HIV-1 antibodies, 195 were reactive for HIV-1 and 5 were falsely nonreactive (1 anti-HTLV-II Ab positive, 1 cancer patient, 1 with elevated IgG, and 2 RPR positive). Of the 199 UMC samples spiked with low levels of HIV-2 antibodies, 196 were reactive for HIV-2 and 3 were falsely nonreactive (1 each positive for antibodies to HSV, HTLV-II, and VZV).

Multispot HIV-1/HIV-2 Reproducibility Testing

The reproducibility of Multispot HIV-1/HIV-2 was evaluated at 5 sites with a panel of 7 specimens tested by 9 operators on 3 days on 3 lots at each site. A total of 6 kit lots were evaluated in this study. The intensity of each spot was scored, and the overall interpretation for each specimen was determined based on the scoring pattern. A total of 566 tests were performed (81 replicates of 7 panel members, minus one sample vial with inadequate volume for testing). The results from all of the sites demonstrate that for strong reactive HIV-1 and HIV-2 specimens and negative specimens, the reproducibility of the Multispot HIV-1/HIV-2 was 100%. The reproducibility of weakly reactive specimens was also acceptable, ranging from 90.1 – 100% agreement on specimens that were

prepared by dilution of a strong reactive sample, and 98.8 - 100% agreement on HIV dual reactive specimens. In summary, overall reproducibility on all 566 tests was 98.0%.

14 – USE OF MULTISPOT AS AN ANTIBODY DIFFERENTIATION TEST IN A DIAGNOSTIC TESTING ALGORITHM

When the Multispot HIV-1/HIV-2 Rapid Test is used as an HIV-1/HIV-2 antibody differentiation assay in a diagnostic testing algorithm for HIV, as recommended by the Clinical Laboratory Standards Institute (CLSI)³², follow the previous instructions in Sections 5 – 10 and Section 12 to perform the test. The following instructions for result appearance and interpretation are used in place of the instructions in Section 11 that describe use of the assay as a rapid HIV-1/HIV-2 test.

Test Result Appearance and Interpretation – Diagnostic Testing Algorithm that Includes Differentiation between HIV-1 and HIV-2 Antibodies

Place the Cartridges with the patient ID label facing toward the operator prior to reading test results. Examine the Cartridge membrane and compare the location of colored spots to the diagram below. The appearance of a definite purple color in any of the Test Spots must be considered as presence of that Spot. Follow guidelines for using the assay in an HIV testing algorithm.³²

Interpretation for Diagnostic Testing Algorithm that Differentiates HIV-1 and HIV-2 Antibodies:**Nonreactive**

↑ Label

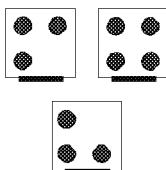
Only the Procedural Control Spot shows purple color development. The 3 Test Spots show no color development. Test result is interpreted as negative for HIV-1 and HIV-2 antibodies. Additional testing is recommended, including HIV nucleic acid testing (NAT).

Reactive**HIV-1 POSITIVE:**

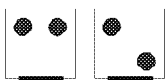
The Procedural Control Spot shows purple color development and **both** the recombinant HIV-1 Spot and the HIV-1 Peptide Spot show purple color development. Test result is interpreted as Positive for HIV-1 antibodies

**HIV-2 POSITIVE**

The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development. Test result is interpreted as Positive for HIV-2 antibodies

**HIV POSITIVE (Undifferentiated):**

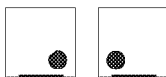
The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development as well as one or both HIV-1 Spots. In this case, the specimen may be tested by additional methods which allow for differentiation between HIV-1 and HIV-2. See dilutional procedure which follows.

Indeterminate

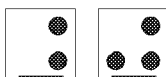
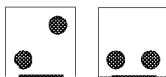
HIV-1 INDETERMINATE: The Procedural Control Spot shows purple color development and either the recombinant HIV-1 Spot or the HIV-1 Peptide Spot shows purple color development, but not both HIV-1 Spots. Test result is interpreted as Indeterminate for HIV-1 antibodies and testing for HIV nucleic acid is recommended.

Invalid - Do not report any results

If no color develops in the Procedural Control Spot, regardless of color development anywhere else on the membrane, the results are **INVALID**. (See examples.)



If the background on the membrane is dark and interferes with the interpretation of the spots, the results are invalid. In addition, if there are stray purple marks or discoloration that interferes with reading the spots, the assay should be repeated. Repeat the assay, and if results are still invalid collect a fresh sample or test by another method.



Note: The appearance of a definite purple color in any of the Test Spots must be considered as presence of that Spot.

Dilutional Procedure for Diagnostic Testing Algorithm that Differentiates HIV-1 and HIV-2 Antibodies


















The following procedure is used to differentiate samples that demonstrate purple color development in the HIV-2 Spot as well as in one or both of the HIV-1 Spots.

1. Dilute the specimen 1:10 (using a calibrated pipettor, add 90 μ L of Negative Control Serum and 10 μ L of sample to a separate test tube; or, alternatively, 135 μ L of Negative Control Serum and 15 μ L of sample). Mix well.
2. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:10 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
3. Read the results according to the criteria below in Test Result Interpretation – Dilutional Testing for Diagnostic Testing Algorithm.


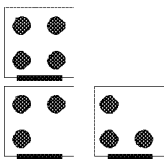





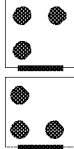
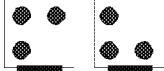




- If the Procedural Control Spot is reactive and the Test Spots are nonreactive at this dilution, the specimen should be interpreted as **“POSITIVE for antibodies to HIV (undifferentiated).”**
 - If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as POSITIVE for antibodies to the specific HIV type identified. For dilutional testing, a result is considered positive for HIV-1 if at least one of the HIV-1 spots is reactive. It is not required to have both HIV-1 spots as reactive in dilutional testing as long as both were reactive when tested undiluted. Refer to the table below for interpretation criteria.
 - If a sample is reactive for one HIV-1 spot and the HIV-2 spot on initial testing and is only reactive for the HIV-1 spot on dilutional testing, that sample should be interpreted as HIV-1 INDETERMINATE.
 - If one or both of the HIV-1 Spots and the HIV-2 Spot are still reactive, continue testing as follows.
4. Dilute the 1:10 diluted specimen again by 10-fold in Negative Control Serum, following the procedure in step 1 above (the final dilution is 1:100).
 5. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:100 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
 6. Read the results according to the criteria below in Test Result Interpretation – Dilutional Testing for Diagnostic Testing Algorithm.
 - If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as POSITIVE for antibodies to the specific HIV type identified. For dilutional testing, a result is considered positive for HIV-1 if at least one of the HIV-1 spots is reactive. It is not required to have both HIV-1 spots as reactive in dilutional testing as long as both were reactive when tested undiluted. Refer to the table below for interpretation criteria.
 - If the dual HIV reactivity does not disappear at the 1:100 dilution, or if the HIV-1 and HIV-2 spots both become nonreactive at the same dilution, the specimen should be interpreted as **“POSITIVE for antibodies to HIV (undifferentiated).”**
 - If a sample is reactive for one HIV-1 spot and the HIV-2 spot on initial testing and testing at a 1:10 dilution, and is only reactive for the HIV-1 spot on dilutional testing, that sample should be interpreted as HIV-1 INDETERMINATE.

Follow CDC guidelines for counseling, testing, and referral when informing test subjects of these HIV test results and their interpretation.⁴²

Test Result Interpretation – Dilutional Testing for Diagnostic Testing Algorithm**1:10 Dilutional testing:**

Initial Result	1:10 Dilutional Result	Interpretation/Action
	  	HIV-1 POSITIVE
		HIV-2 POSITIVE
	 	Retest at 1:100 dilution
		Retest at 1:100 dilution
		HIV POSITIVE (undifferentiated)
 	 	HIV-1 INDETERMINATE
		HIV-2 POSITIVE
	 	Retest at 1:100 dilution
		HIV POSITIVE (undifferentiated)

1:100 Dilutional Testing:

Initial Result	1:10 Dilutional Result	1:100 Dilutional Result	Interpretation
			HIV-1 POSITIVE
			HIV-2 POSITIVE
			HIV POSITIVE (undifferentiated)
			HIV POSITIVE (undifferentiated)
			HIV POSITIVE (undifferentiated)
			HIV-1 INDETERMINATE
			HIV-2 POSITIVE
			HIV POSITIVE (undifferentiated)
			HIV POSITIVE (undifferentiated)

15. PERFORMANCE CHARACTERISTICS OF MULTISPOT IN A DIAGNOSTIC TESTING ALGORITHM

The CDC and several public health laboratories have evaluated the use of the Multispot HIV-1/HIV-2 Rapid Test as the HIV-1/HIV-2 antibody differentiation assay in a diagnostic testing algorithm, after repeatedly reactive results were obtained from an HIV-1/2 antibody immunoassay or HIV antigen/antibody combination assay. The studies were conducted on specimens that had been submitted for clinical testing. Results of the algorithm using Multispot were compared to test results from an HIV-1 Western blot, an HIV-1 qualitative RNA assay, or both. Some specimens were also tested with an HIV-2 EIA or HIV-2 qualitative RNA assay. Results of these studies documenting performance of the Multispot as the HIV-1/HIV-2 antibody differentiation assay in the diagnostic testing algorithm are summarized here.

Study 1: In a CDC study that included use of the Multispot HIV-1/HIV-2 Rapid Test as the differentiation assay in a diagnostic testing algorithm, 830 specimens were tested, of which 416 were from individuals with established HIV infection and 414 were HIV negative. The interpretation of Multispot results in this study was based on the rapid testing criteria, and not the criteria described above for use of the assay as an antibody differentiation test in a diagnostic testing algorithm. The Multispot sensitivity observed in this study was 99.52% with a 95% confidence interval of 98.26 – 99.62%. The observed specificity for Multispot in this study was 99.03% with a 95% confidence interval of 97.54 – 99.61%. The specificity observed in this study may have been higher if the diagnostic algorithm interpretive criteria were used (requiring two HIV-1 spots for a reactive test result). This study demonstrated improved sensitivity for detecting acute HIV-1 infections when Multispot was used in the alternative algorithm, while maintaining the ability to accurately detect established HIV-1 infections.³³

Study 2: The Multispot HIV-1/HIV-2 Rapid Test was evaluated retrospectively by CDC using test results from a public health laboratory to assess the ability to accurately differentiate HIV-1 and HIV-2 infections in individuals known to be infected with HIV. Multispot was positive in 1788/1790 specimens that were HIV-1 Western blot positive by the CDC criteria³⁴, and negative in 2/1790. Six specimens in this study were confirmed as HIV-2 by a research-use HIV-2 Western blot and DNA NAT, of which four were positive on Multispot for HIV-2 only and two were undifferentiated. Multispot correctly identified HIV-1 infection in specimens that were not identified as positive by Western blot, including at least 15% (15/96) of the specimens that were HIV-1 Western blot indeterminate and 1% (2/249) of those that were negative by Western blot. Two HIV-1 Western blot indeterminate results had discordant results between Multispot and follow-up test results: one specimen was undifferentiated on Multispot and HIV negative on follow-up testing and one specimen was negative on Multispot and confirmed HIV-1 positive on follow-up testing. The appearance of test results (reactivity for one or both HIV-1 spots) and the results of dilutional testing were not reported in this study. No information was provided on the interpretive criteria used in this study (original diagnostic criteria [requiring only one HIV-1 spot for a positive interpretation] or the diagnostic algorithm interpretive criteria [requiring two HIV-1 spots for a positive interpretation]), nor were the results of dilutional testing. This study demonstrated that the Multispot HIV-1/HIV-2 Rapid Test can correctly identify HIV-2 infected individuals and that the performance of the Multispot HIV-1/HIV-2 is comparable or exceeds that of an HIV-1 Western blot when used in the HIV diagnostic testing algorithm.³⁵

Study 3: A separate study to assess the use of Multispot as an HIV-1/HIV-2 differentiation assay for confirmation of repeatedly reactive EIA results included the testing of the 38,257 specimens, of which 1578 were identified as HIV-1 positive in the testing algorithm based either on a positive HIV-1 Western blot (n=1546), detectable HIV-1 RNA (n=29), or follow-up specimen results (n=3). Using the interpretive criteria that require only one HIV-1 spot to be reactive for a positive interpretation, 1575/1578 (99.8%) of specimens were classified as HIV-1 reactive by Multispot and three were non-reactive or undifferentiated by Multispot. Of the 1562 specimens that were reactive for both HIV-1 spots, two identified as HIV-1 positive on Multispot were Western blot indeterminate with envelope reactivity (including gp41 or gp160) indicating the samples were likely positive, although false positive results could not be ruled out. Thirteen specimens out of the 1578 were reactive for only one HIV-1 spot (interpretation of Multispot indeterminate), of which 11 were true positives as confirmed by HIV-1 Western blot (n=4), NAT (n=6) or follow-up specimen testing (n=1).³⁶ This study demonstrated that the performance of the Multispot HIV-1/HIV-2 Rapid Test is comparable to HIV-1 Western blot when used in the HIV diagnostic testing algorithm.

Study 4: A study was performed at a public health laboratory to compare the Multispot HIV-1/HIV-2 Rapid Test to Western blot for use in a confirmatory testing algorithm for HIV. Multispot identified 8670/8678 HIV-1 Western blot positive specimens giving a sensitivity of 99.91% based on positive Western blot as the gold standard. An additional 26 specimens were positive by Multispot, of which 3 specimens were negative on Western blot and were identified as positive for HIV-1, and 23/63 specimens were indeterminate on Western blot and were identified as positive for HIV-1 (11 specimens) or positive for HIV-2 (12 specimens).³⁷ This study demonstrated that using the Multispot HIV-1/HIV-2 Rapid Test in the HIV diagnostic testing algorithm identified additional specimens as HIV-1 positive or HIV-2 positive that were indeterminate on HIV-1 Western blot.

Study 5: The performance of the diagnostic testing algorithm that uses the Multispot HIV-1/HIV-2 Rapid Test to differentiate HIV-1 from HIV-2 was evaluated in a study that included 2090 HIV-1 Western blot positive specimens and 1508 blood donors that were HIV negative by immunoassay and HIV-1 NAT. The observed Multispot sensitivity when used as a rapid test was 99.95% with a 95% confidence interval of 99.73 – 100% compared to HIV-1 Western blot n=2090). The specificity was 99.40% with a 95% confidence interval of 98.87 – 99.73% (n=1508).³⁸ This study demonstrated that the performance of the Multispot HIV-1/HIV-2 Rapid Test is comparable to HIV-1 Western blot when used in the HIV diagnostic testing algorithm.

16. BIBLIOGRAPHY

1. Centers for Disease Control: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. **Morbidity and Mortality Weekly Rep** 37:377-388, 1988.
2. Centers for Disease Control: Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. **Morbidity and Mortality Weekly Rep** 34:5-7, 1985.
3. Delmonico FL, Snyderman DR: Organ donor screening for infectious diseases. **Transplantation** 65(5):603-610, 1998.
4. Barre-Sinoussi F, Chermann JC, Rey F, et al: Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). **Science** 220:868-871, 1983.
5. Gallo RC, Salahuddin SZ, Popovic M, et al: Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. **Science** 224:500-503, 1984.
6. Coffin J, Haase A, Levy JA, et al: What to call the AIDS virus? **Nature** 321:10, 1986.
7. Clavel F, Guetard D, Brun-Vezinet F: Isolation of a new human retrovirus from West African patients with AIDS. **Science** 233:343-346, 1986.
8. Clavel F, Manshino K, Chameret S, et al: Human immunodeficiency virus type 2 infection associated with AIDS in West Africa. **New Engl J Med** 316:1180-1185, 1987.
9. Schim van der Loeff MF and Aaby P: Towards a better understanding of the epidemiology of HIV-2. **AIDS** 13 (Suppl. A):S69-S84, 1999.
10. Centers for Disease Control: AIDS due to HIV-2 infection - New Jersey. **Morbidity and Mortality Weekly Rep** 37:33-35, 1988.
11. Hoff R, Weiblen BJ, Schwerzler M, et al: Specific antibodies to HIV-2 detected in an anonymous newborn blood specimen from Massachusetts. **Fourth Consensus Conference on Testing for Human Retroviruses**, March 1989.
12. Ayanian JZ, Maguire JH, Marlink RG, et al: HIV-2 infection in the United States. **New Engl J Med** 320:1422-1423, 1989.
13. O'Brien TR, George JR, Holmberg SD: Human immunodeficiency virus type 2 infection in the United States. **JAMA** 267:2775-2779, 1992.
14. Centers for Disease Control: Update: HIV-2 infection among blood and plasma donors—United States, June 1992-June 1995. **Morbidity and Mortality Weekly Rep** 44:603-606, 1995.
15. Sullivan PS, Fleming PL: Surveillance for HIV-2 in the United States: Update and recommendations for future surveillance. Presented at the Association of Public Health Laboratories Conference, Charlotte, NC, March 6-9, 2000.
16. Brun-Vezinet F, Katlama C, Roulot D, et al: Lymphadenopathy associated virus type 2 in AIDS and AIDS-related complex. **Lancet** 1:128-132, 1987.
17. Quinn TC, Zaccarias FRK, St. John RK: AIDS in the Americas: an emerging public health crisis. **New Engl J Med** 320:1005-1007, 1989.
18. Guyader M, Emerman M, Sonigo P, et al: Genome organization and transactivation of the human immunodeficiency virus type 2. **Nature** 326:662-669, 1987.
19. Cabrian K, Shriver K, Goldstein L, et al: Human immunodeficiency virus type 2: a review. **J Clinical Immunoassay** 11:107-114, 1988.
20. Janssens W, Buvé A, Nkengasong JN: The puzzle of HIV-1 subtypes in Africa. **AIDS** 11:705-712, 1997.
21. Charneau P, Borman AM, Quillant C, et al: Isolation and envelope sequence of a highly divergent HIV-1 isolate: definition of a new HIV-1 group. **Virology** 205:247-253, 1994.
22. Simon F, Maucière P, Rogues P, et al: Identification of a new human immunodeficiency virus type 1 distinct from group M and group O. **Nature Medicine** 4:1032-1037, 1998.
23. Gao F, Yue L, Robertson DL, et al: Genetic diversity of human immunodeficiency virus type 2: evidence for distinct subtypes with differences in virus biology. **J Virology** 68:7433-7447, 1994.
24. George JR, Rayfield M, Philips S, et al: Efficacies of U.S. FDA-licensed HIV-1 screening enzyme immunoassays for detecting antibodies to HIV-2. **AIDS** 4:321-326, 1990.
25. Starcich BR, Hahn BH, Shaw GM, et al: Identification and characterization of conserved and variable regions in the envelope gene of HTLV-III/LAV, the retrovirus of AIDS. **Cell** 45:637-648, 1986.

26. Wang JJG, Steel S, Wisniewolski R, Wang CY: Detection of antibodies to human T-lymphotrophic virus type III by using a synthetic peptide of 21 amino acid residues corresponding to a highly antigenic segment of gp41 envelope protein. **Proc Nat Acad Sci USA** 83:6159-6163, 1986.
27. Cosand WL: Synthetic antigen for the detection of AIDS-related disease. U.S. Patent #4,629,783, 1986.
28. Fenouillet E, Sorensen A-M, Lacroix M, Coutellier A, Herson S, Fretz-Foucault C, Gluckman J-C: Early and specific diagnosis of seropositivity to HIVs by an enzyme-linked immunosorbent assay using env-derived synthetic peptides. **AIDS** 4:1137-41, 1990.
29. Gnann JW, McCormick, Mitchell S, Nelson J, Oldstone MBA: Synthetic peptide immunoassay distinguishes HIV type 1 and HIV type 2 infections. **Science** 237:1346-1349, 1987.
30. Gnann JW, Nelson JA, Oldstone MBA: Fine mapping of an immunodominant domain in the transmembrane glycoprotein of human immunodeficiency virus. **J Virol** 61:2639-2641, 1987.
31. Alizon M, Wain-Hobson S, Montagnier L, Sonigo P: Genetic variability of the AIDS virus: nucleotide sequence analysis of two isolates from African patients. **Cell** 46:63-74, 1986.
32. Rosenberg, EC, Brennan CA, et al. Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infections; Approved Guideline Clinical and Laboratory Standards Institute, M53-A. Vol 31. No 13. 2011.
33. Masciotra S, McDougal JS, Feldman J, Sprinkle P, Wesolowski L, Owen SM. Evaluation of an alternative HIV diagnostic algorithm using specimens from seroconversion panels and persons with established HIV infections. **J Clin Virol**. 2011 Dec;52 Suppl 1:S17-22.
34. Centers for Disease Control, Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections. **Morbidity and Mortality Weekly Report** 38(S-7): 1-7, 1989.
35. Nasrullah M, Ethridge SF, Delaney KP, Wesolowski LG, Granade TC, Schwendemann J, Boromisa RD, Heffelfinger JD, Owen SM, Branson BM. Comparison of alternative interpretive criteria for the HIV-1 Western blot and results of the Multispot HIV-1/HIV-2 Rapid Test for classifying HIV-1 and HIV-2 infections. **J Clin Virol** 2011 Dec.:S23-S27.
36. Styer LM, Sullivan TJ, Parker MM. Evaluation of an alternative supplemental testing strategy for HIV diagnosis by retrospective analysis of clinical HIV testing data. **J Clin Virol**. 2011 Dec;52 Suppl 1:S35-40.
37. Torian LV, Forgione LA, Punsalang AE, Pirillo RE, Oleszko WR. Comparison of Multispot EIA with Western blot for confirmatory serodiagnosis of HIV. **J Clin Virol**. 2011 Dec;52 Suppl 1:S41-44.
38. Wesolowski LG, Delaney KP, Hart C, Dawson C, Owen SM, Candal D, Meyer WA 3rd, Ethridge SF, Branson BM. Performance of an alternative laboratory-based algorithm for diagnosis of HIV infection utilizing a third generation immunoassay, a rapid HIV-1/HIV-2 differentiation test and a DNA or RNA-based nucleic acid amplification test in persons with established HIV-1 infection and blood donors. **J Clin Virol**. 2011 Dec;52 Suppl 1:S45-9.
39. Valkirs GE, Barton R: ImmunoConcentration™ - A new format for solid phase immunoassays. **Clin Chem**. 31: 1427-1431, 1985.
40. US Department of Health and Human Services. **Biosafety in Microbiological and Biomedical Laboratories**. 5th ed. Washington, DC: US Government Printing Office, HHS publication No. (CDC) 21-1112. December 2009.
41. World Health Organization. **Laboratory Biosafety Manual**. 3rd ed. Geneva: World Health Organization. 2004.
42. Centers for Disease Control: Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women. **Morbidity and Mortality Weekly Rep** 50:32-35, 2001
43. Rutherford GW, Lifson AR, Hessel NA, et al: Course of HIV infection in a cohort of homosexual and bisexual men: an 11 year follow-up study. **Br Med J** 301: 1183-1188, 1990.
44. Walther-Jallow L, Andersson S, Da Silva Z: High Concordance between Polymerase Chain Reaction and Antibody Testing of Specimens from Individuals Dually Infected with HIV Types 1 and 2 in Guinea-Bissau, West Africa. **AIDS Research and Human Retroviruses** 15: 957-962, 1999.



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EXHIBIT 8

Multispot HIV-1/HIV-2 Rapid Test

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Signature:	Date:
Name: Adam Rosendorff, MD	Title: Laboratory Director

The Laboratory Director or designee will review this procedure at least annually including revisions.

<i>Reviewed By:</i>	<i>Date:</i>	<i>Comments:</i>

	Case 5:18-cr-00258-EJS Document 156-2 Filed 11/19/21 Page 256 of 356 Standard Operating Procedure	Document Number: SOP-002 Revision: A
	CLIA Laboratory	Effective Date: 7/18/2014
Multispot HIV-1/HIV-2 Rapid Test		

Multispot HIV-1/HIV-2 Rapid Test

Rapid Enzyme Immunoassay to be used as a diagnostic aid for the detection and differentiation of HIV-1 and HIV-2 antibodies in human serum or plasma.

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13. USE OF MULTISPOT AS AN ANTIBODY DIFFERENTIATION ASSAY IN A DIAGNOSTIC TESTING ALGORITHM
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Multispot HIV-1/HIV-2 Rapid Test

1 - NAME AND INTENDED USE

The Multispot HIV-1/HIV-2 Rapid Test is a single use qualitative immunoassay to detect and differentiate circulating antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1, HIV-2) in fresh or frozen human serum and plasma. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in fresh or frozen human serum or plasma. This test is suitable for use in multi-test algorithms designed for statistical validation of an HIV screening test result or as part of an HIV-1/HIV-2 diagnostic testing algorithm that includes differentiation of HIV-1 and HIV-2 antibodies.

2 - SUMMARY AND EXPLANATION OF THE TEST

Acquired Immunodeficiency Syndrome (AIDS) is caused by viruses transmitted by sexual contact, exposure to blood (including sharing contaminated needles and syringes) or certain blood products, or transmitted from an infected mother to her fetus or child during the perinatal period.² Additionally, transmission of the viruses can occur through tissue transplantation.³ Human Immunodeficiency Virus Type 1 (HIV-1) has been isolated from patients with AIDS and AIDS-related complex (ARC).⁴⁻⁶ HIV-1 was thought to be the sole causative agent of these syndromes until 1986, when a second type of Human Immunodeficiency Virus (Human Immunodeficiency Virus Type 2 or HIV-2) was isolated and also reported to cause AIDS.⁷⁻⁸ Since the initial discovery, hundreds of cases of HIV-2 infection have been documented worldwide.⁹ In the United States, there have been more than 80 cases of infection with HIV-2 reported, including two blood donors.¹⁰⁻¹⁵

This second immunodeficiency virus (HIV-2) is similar to, but distinct from, HIV-1. Both viruses have similar morphology and lymphotropism,¹⁶ and the modes of transmission appear to be identical.^{9,17} The HIV-1 and HIV-2 genomes exhibit about 60% homology in conserved genes such as gag and pol, and 39-45% homology in the envelope genes.¹⁸ Serologic studies have also shown that the core proteins of HIV-1 and HIV-2 display frequent cross-reactivity whereas the envelope proteins are more type-specific.¹⁹

Within the two major HIV types, there is significant variation, as well. By analyzing sequences of representative strains, HIV-1 has been divided into three groups: group M (for major), including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non-O).²⁰⁻²² Similarly, the HIV-2 strains have been classified into at least five subtypes (A through E).²³ Some HIV-1 variants share ≤50% homology in their envelope genes with the sequences of more common prototype strains.

Multispot HIV-1/HIV-2 Rapid Test

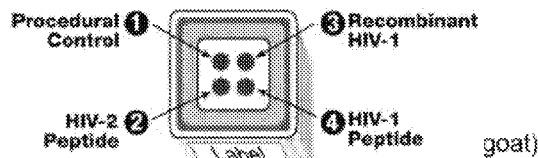
Despite some degree of immunological cross-reactivity between types and subtypes of HIV, reliable detection of antibodies derived from the more divergent strains may only be achieved by incorporating type-specific protein sequences into the assay design. In one study, detection of HIV-2 positive samples by HIV-1 antibody kits ranged from 60% to 91%, depending on the test used.²⁴ The Multispot HIV-1/HIV-2 Rapid Test incorporates highly conserved recombinant and synthetic peptide sequences representing HIV-1 and HIV-2 envelope proteins.²⁵⁻³¹ The Multispot HIV-1/HIV-2 Rapid Test is designed to detect antibodies to HIV-1 and HIV-2 in serum or plasma rapidly and reliably without instrumentation. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results or as part of an HIV-1/HIV-2 diagnostic testing algorithm that includes differentiation of HIV-1 and HIV-2 antibodies.³²⁻³⁸

3 - BIOLOGICAL PRINCIPLE OF THE TEST

The Multispot HIV-1/HIV-2 Rapid Test is based on the principle of ImmunoConcentration™.³⁹ The Multispot HIV-1/HIV-2 Cartridge contains a removable specimen prefilter, the reaction membrane, and an absorbent pad. All of the liquids added to the Cartridge are absorbed by the pad and contained within the Cartridge. When the test is completed, the entire Cartridge can be decontaminated by standard laboratory practices and properly discarded.

Microscopic particles are separately coated with the antigens that represent portions of the transmembrane proteins HIV-1 and HIV-2, respectively. The microparticles are immobilized on the reaction membrane of the Multispot HIV-1/HIV-2 Cartridge and form the Test Spots. The reaction membrane also contains a Procedural Control Spot that serves as a control spot to ensure that the entire test procedure was properly executed. Samples to be tested are diluted in Specimen Diluent and then added to the prefilter in the Cartridge. After the diluted specimen has been completely absorbed, the prefilter is removed. If antibodies against HIV-1 and/or HIV-2 are present in the specimen, they bind to the antigens on the microparticles in the specific spots on the cartridge membrane. The Conjugate, which contains alkaline phosphatase-labeled goat anti-human IgG (H+L chain specific), is then added to the Cartridge. The Conjugate binds to the human antibody-antigen complexes that are immobilized in the spots on the cartridge membrane. Unbound Conjugate is removed by a wash step.

Next, Development Reagent is added to the Cartridge. A purple color develops on the Test Spots in proportion to the amount of antibodies against HIV-1 and/or HIV-2 that have been bound to the antigen-coated microparticles and detected by the Conjugate. A purple color will also develop on the Procedural Control Spot when the test has been performed correctly. Color development is stopped by the addition of Stop Solution. The membrane is examined visually for the presence of purple color on the Procedural Control Spot and on the Test Spots.



- (2) HIV-2 Peptide: Peptide representing the immunodominant epitope of the HIV-2 virus gp36 envelope glycoprotein.
- (3) Recombinant HIV-1: Recombinant gp41 (HIV-1 envelope glycoprotein) expressed in *E. coli* (gp41
- (4) HIV-1 Peptide: Peptide representing the immunodominant epitope of the HIV-1 virus gp41 envelope glycoprotein

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Standard Operating Procedure

Document Number: SOP-002

CLIA Laboratory

Revision: A

Effective Date: 7/18/2014

Multispot HIV-1/HIV-2 Rapid Test

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Multispot HIV-1/HIV-2 Rapid Test

4- REAGENTS

MULTISPOT HIV-1/HIV-2 Rapid Test Product No. 25228 (50 Tests)

Component	Contents	Preparation
1 • Multispot HIV-1/HIV-2 Cartridge (50)	• Foil-sealed base container with specimen prefilter; Membrane with 1 Procedural Control Spot and 3 Test Spots	Remove foil seal before use.
2 • Positive Control Serum 1 dropper bottle (1 mL)	• Heat-inactivated human serum/plasma containing anti-HIV-1 and anti-HIV-2 immunoglobulin; Nonreactive for HBsAg and antibody to HCV • 0.1% Sodium azide • 0.5% ProClin™ 300	Dilute in Specimen Diluent as described.
3 • Negative Control Serum 1 dropper bottle (1 mL)	• Human serum; Nonreactive for HBsAg and antibody to HIV and HCV • 0.1% Sodium azide • 0.5% ProClin™ 300	Dilute in Specimen Diluent as described.
4 • Specimen Diluent 1 dropper bottle (25 mL)	• Diluent for specimens and Controls • 0.1% ProClin™ 150 • 0.125% ProClin™ 300	Dispense with dropper provided.
5 • Conjugate 1 dropper bottle (9.5 mL)	• Anti-human IgG (H+L) (goat) alkaline phosphatase conjugated solution • 0.1% ProClin™ 150	Ready to use as supplied.
6 • Wash Solution 2 dropper bottles (2 x 85 mL)	• TRIS • Urea • Propylene glycol • Nitroblue tetrazolium • 0.1% ProClin™ 150	Ready to use as supplied.
7 • Development Reagent 1 dropper bottle (8.5 mL)	• 3-Indoxyl phosphate	Ready to use as supplied.
8 • Stop Solution 1 dropper bottle (55 mL)	• 0.1 N H ₂ SO ₄ (sulfuric acid)	Ready to use as supplied.
9 • Disposable Transfer Pipets (60)	• Polyethylene transfer pipets	Ready to use as supplied.
10 • Eyedropper (1)	• Polyethylene eyedropper and cap with rubber bulb; Contains Dry Natural Rubber, a potential sensitizer	Use in Specimen Diluent bottle.

Multispot HIV-1/HIV-2 Rapid Test

5. The Multispot HIV-1/HIV-2 Rapid Test contains human blood components. No known test method can offer complete assurance that infectious agents are absent. Therefore, all human blood derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended *Universal Precautions* for bloodborne pathogens as defined by OSHA, Biosafety Level 2 guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*⁽⁴⁰⁾, WHO *Laboratory Biosafety Manual*⁽⁴¹⁾, and/or local, regional and national regulations. The following human blood derivatives are found in this kit:



- a The **Positive Control Serum** has been heat-treated to inactivate HIV viruses and has been tested and found nonreactive for Hepatitis B Surface Antigen (HBsAg) and antibodies to Hepatitis C virus (HCV Ab).
- b The **human source material used in the preparation of the Negative Control Serum** has been tested and found nonreactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C virus (HCV Ab), and antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2 Ab).

Biological spills: Human source material spills should be treated as potentially infectious.

Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment with an appropriate chemical disinfectant that is effective for the potential biohazards relative to the samples involved (commonly a 1:10 dilution of bleach, 70- 80% ethanol or isopropanol, an iodophor (such as 0.5% Wescodyne™ Plus), or a phenolic, etc.) and wiped dry.

Spills containing acid should be appropriately absorbed (wiped up) or neutralized, wiped dry and then the area wiped with one of the chemical disinfectants; material used to absorb the spill may require biohazardous waste disposal.

NOTE: DO NOT PLACE SOLUTIONS CONTAINING BLEACH INTO THE AUTOCLAVE.

6- PRECAUTIONS FOR USERS**Safety Precautions:**

1. This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Handle appropriately with the requisite Good Laboratory Practices. Wear appropriate protective clothing, including lab coat, eye/face protection and disposable gloves (synthetic, non-latex gloves are recommended) while handling kit reagents and patient samples. Wash hands thoroughly after performing the test.
2. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
3. Do not pipette by mouth.
4. **This Product Contains Dry Natural Rubber in the dropper bulb used with the Specimen Diluent bottle.**
5. **Dispose of all specimens and materials used to perform the test as biohazardous waste. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations. For additional information on biosafety requirements, refer to CDC recommendations for Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens.¹**
6. Complete hazard information and precautions are located in the Safety Data Sheet (SDS) available at bio-rad.com or upon request.

Handling precautions:

1. Do not use any kit components beyond their stated expiration date.

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Multispot HIV-1/HIV-2 Rapid Test

2. Do not mix components from different lots.
3. Do not use the components in any other type of test kit as a substitute for the components in this test kit.
4. Use the Multispot HIV-1/HIV-2 Cartridge and disposable Transfer Pipets only once and then dispose of as described in Safety Precautions. Do not reuse these kit components.
5. Exercise care in opening and reusing reagent bottles to avoid microbial contamination of the reagents.
6. Prior to running the assay, verify that the prefilter is seated firmly on top of the Cartridge by pressing down firmly and evenly.
7. Always hold each reagent bottle vertically and allow each reagent to fall freely from the dropper tip. Do not touch the dropper tip to any surface; this may contaminate the reagent.
8. Avoid contact of the Stop Solution with any oxidizing agent. Do not allow Stop Solution to come into contact with metals.
9. Handle the Negative and Positive Control Serums in the same manner as patient specimens.
10. Inadequate adherence to package insert instructions may result in erroneous results.
11. When removing the Transfer Pipets from the bag, avoid touching the tips of the pipets.
12. The test should be performed with Cartridges that are placed on a flat surface.
13. Adequate lighting is required to read test results.

7- REAGENT PREPARATION AND STORAGE

All solutions and reagents are ready to use as supplied. Store kit at 2-8°C or room temperature (20-30°C). If stored at 2-8°C, bring all reagents to room temperature before use, and return entire kit to 2-8°C when not in use. The kit may be used up to kit expiration when stored at 2-8°C or for up to 3 months if stored at room temperature. When stored at room temperature, change the expiration date to three months after start of room temperature storage (do not change the date if less than 3 months expiration remains on the kit). Do not freeze test components.

8- SPECIMEN COLLECTION, PREPARATION, AND STORAGE

Fresh or frozen serum or plasma collected by standard phlebotomy procedures may be used in the test. The minimally acceptable volume of specimen available for performing the test is 40 µL. Approximately 30 µL is used for running each test. No clinically significant effect has been detected in assay results of serum or plasma samples with increased levels of hemoglobin, protein, albumin, lipids, or bilirubin. **Performance of this assay has not been evaluated on patient samples that have been heat-inactivated.**

The following anticoagulants have been evaluated and found to be acceptable for use with this test: EDTA, sodium citrate, sodium heparin, and SST tubes. Samples that are collected into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution. **Use of other anticoagulants has not been evaluated and may give incorrect results.**

Specimens may be stored at 2-8°C for 7 days or at room temperature (20-30°C) for up to 48 hours. For long-term storage, the specimens should be frozen (-20°C or colder). Specimens may be frozen and thawed up to 5 times.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

9- MULTISPOT HIV-1/HIV-2 RAPID TEST PROCEDURE**Materials Provided**

See REAGENTS section on page 5.

Additional Materials provided which are included in the kit:

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Multispot HIV-1/HIV-2 Rapid Test

- Package insert (1)
- Subject Information Notice (1) - The Notice in the kit box may be copied as needed.
- Customer letter (1)

Materials Required But Not Provided

7. Disposable glass or polypropylene test tubes (do not use polystyrene) to prepare diluted specimens and controls (for example: 12 x 75 mm tubes)
2. Test tube racks
3. Absorbent pads or paper towels
4. Biohazard bags with closures
5. Household bleach (5% or 8% sodium hypochlorite), diluted to a minimum concentration of 10% bleach (0.5% sodium hypochlorite). Alternative disinfectants include 70% ethanol or 0.5% Wescodyne™.
6. Disposable gloves.
7. Laboratory timer.
8. Precision pipettors that deliver 30 µL and 300 µL (optional for addition of specimen and Specimen Diluent). Precision pipettors that deliver 10 µL and 90 µL as needed for dilutional testing of dually positive samples.
9. Indelible laboratory marker.

Preliminary Statements

1. **Once testing has been started, it should be completed without interruption.**
2. Do not use more than ten (10) Multispot HIV-1/HIV-2 Cartridges in a batch, since using more Cartridges may make it difficult to complete the testing without interruption. Larger numbers of specimens can be tested by running several batches of up to 10 Cartridges.
3. The eyedropper used to dispense Specimen Diluent is packaged separately from the bottle of Specimen Diluent. The first time a kit is used, remove the eyedropper from the packaging and insert it into the bottle of Specimen Diluent. Discard the original cap and use the eyedropper as the cap for the bottle. Two full eyedroppers dispenses approximately 300 µL of Specimen Diluent.
4. A 30µL precision pipettor can be used for addition of the sample to the Specimen Diluent. The disposable Transfer Pipets supplied in the kit dispense approximately 30 µL per drop.
5. The Cartridges should be placed on a flat surface during the assay procedure to ensure proper flow of specimen and reagents through the membrane.
6. **All solutions must be completely absorbed (no standing liquid) into the Cartridge membrane before proceeding to the next step in the Assay Procedure.**

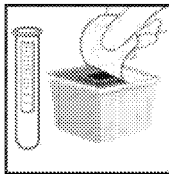
Assay Procedure

1. **Bring kit and specimens to room temperature (20-30°C) before beginning testing. It is essential that all kit components are at room temperature before use.**
2. **Place the required number of Cartridges on a flat surface with the patient ID label facing toward the operator.** Peel away the foil seals and discard them. Label the Cartridges to correspond with the test tubes and the specimens to be tested.
Note: Verify that the blue prefilter and gray top support are seated securely in the base of the Cartridge by pressing down firmly and evenly on both pieces. The prefilter must be present in order to use the Cartridge for testing.
3. **Label a test tube for each specimen or control to be tested.**
4. **Invert the Specimen Diluent bottle ten times to thoroughly mix just prior to drawing the reagent.**
5. **Add two full eyedroppers of Specimen Diluent to each specimen and control tube.**
Note: With the eyedropper in the Specimen Diluent, hold vertically and squeeze the bulb

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Multispot HIV-1/HIV-2 Rapid Test

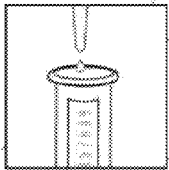
16. **Fill the central well of each Cartridge with Stop Solution** by holding the bottle vertically and squeezing gently. ***Wait for the Stop Solution to be absorbed completely before reading results.***
17. Read test results according to Test Result Appearance and Interpretation, Section 11 (Rapid Testing) or Section 14 (Antibody Differentiation Test in a Diagnostic Testing Algorithm), either immediately or anytime up to 4 hours after completing the test. An elevated background can appear over time with some specimens; therefore, reading results within 1 hour is optimal.



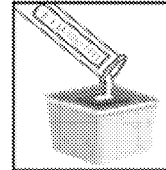
1. Remove foil; press prefilter down. Label cartridge and specimen or control test tubes.



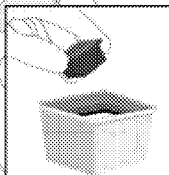
2. Add 2 full droppers of Specimen Diluent to each test tube.



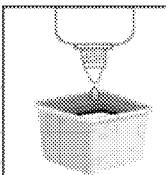
3. Add one drop of each sample or control to each labeled tube using a transfer pipette. Mix well.



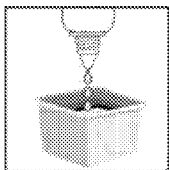
4. Pour each sample into the prefilter of the labeled cartridge. Wait 2 minutes.



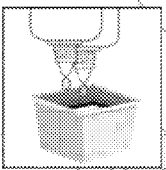
5. Remove and discard prefilter.



6. Fill the central well of each cartridge with Wash Solution.



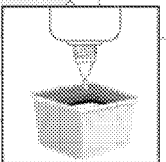
7. Once absorbed, add 3 drops of Conjugate. Wait 2 minutes.



8. Fill well with Wash Solution and let absorb. Repeat.



9. Add 3 drops of Development Reagent. Wait 5 minutes.



10. Fill well with Stop Solution. Allow to absorb and read results.

Multispot HIV-1/HIV-2 Rapid Test**10- QUALITY CONTROL – VALIDATION OF RESULTS****Procedural Control**

Each Multispot HIV-1/HIV-2 Cartridge has a built-in procedural control, the Procedural Control Spot, which is used to determine validity of the assay. The Procedural Control Spot must be reactive (a definite purple spot) on each Cartridge for the results of that Cartridge to be valid.

Quality Control

Using individual Multispot HIV-1/HIV-2 Cartridges as described in the Assay Procedure above, run 1 Positive Control Serum and 1 Negative Control Serum (both provided in the kit) under the following circumstances to monitor proper test performance:

- A new operator uses the kit, prior to performing testing of specimens.
- A new test kit lot is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit falls outside of 2-30°C (35.6-86°F).
- The temperature of the test area falls outside of 20-30°C (68-86°F).
- According to intervals defined by the testing facility.

Results are read by examining the membrane and comparing the location of colored spots on the membrane to the diagram below. **Position the Multispot HIV-1/HIV-2 Cartridge with the ID label facing the user.** The appearance of any purple color in any of the Test Spots, regardless of intensity, must be considered as presence of that Spot.

Expected results are as follows:

**Negative Control**

Only the Procedural Control Spot shows purple color development. The 3 Test Spots show no color development.

Note placement of Cartridge ID label.

**Positive Control**

The Procedural Control Spot, both HIV-1 Test Spots, and the HIV-2 Test Spot show purple color development.

11- TEST RESULT APPEARANCE AND INTERPRETATION – RAPID HIV-1/HIV-2 TESTING

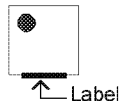
Note: For interpretation of the assay when used as the differentiation assay in a diagnostic testing algorithm, refer to Section 14 - USE OF MULTISPOT AS THE ANTIBODY DIFFERENTIATION TEST IN A DIAGNOSTIC TESTING ALGORITHM

Place the Cartridges with the patient ID label facing toward the operator prior to reading test results. Examine the Cartridge membrane and compare the location of colored spots to the diagram below. The appearance of any purple color must be considered as presence of that Spot. Follow the CDC guidelines for counseling, testing, and referral when informing test subjects of these HIV test results and their interpretation.⁴²

Multispot HIV-1/HIV-2 Rapid Test

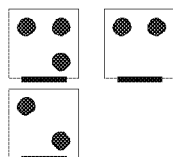
Interpretation for Rapid HIV-1/HIV-2 Testing:

Nonreactive - Report results as described in the CDC guidance for reporting test results and interpretation.⁴²



Only the Procedural Control Spot shows purple color development. The 3 Test Spots show no color development. Test result is interpreted as negative for HIV-1 and HIV-2 antibodies.

Reactive (Preliminary Positive) - Report results as described in the CDC guidance for reporting test results and interpretation.⁴²



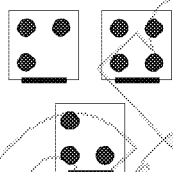
HIV-1 Reactive - Preliminary Positive:

The Procedural Control Spot shows purple color development and the recombinant HIV-1 Spot and/or the HIV-1 Peptide Spot show purple color development. Test result is interpreted as Preliminary Positive for HIV-1 antibodies.



HIV-2 Reactive - Preliminary Positive:

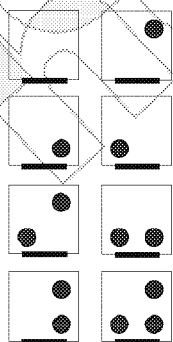
The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development. Test result is interpreted as Preliminary Positive for HIV-2 antibodies.



HIV Reactive (Undifferentiated) - Preliminary Positive:

The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development as well as one or both HIV-1 Spots. In this case, the specimen may be tested by additional methods which allow for differentiation between HIV-1 and HIV-2. See dilutional procedure which follows.

Invalid - Do not report any results



If no color develops in the Procedural Control Spot, regardless of color development anywhere else on the membrane, the results are **INVALID**. (See examples.)

If the background on the membrane is dark and interferes with the interpretation of the spots, the results are invalid. In addition, if there are stray purple marks or discoloration that interfere with reading the spots, the assay should be repeated. Repeat the assay, and if results are still invalid collect a fresh sample or test by another method.

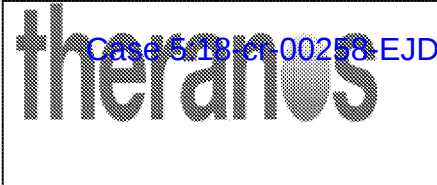
Note: The appearance of any purple color in any of the Test Spots, regardless of intensity, must be considered as presence of that Spot.

Dilutional Procedure for HIV Differentiation – Rapid HIV-1/HIV-2 Testing

The following procedure is used to differentiate samples that demonstrate purple color development in the HIV-2 Spot as well as in one or both of the HIV-1 Spots.

8. Dilute the specimen 1:10 (using a calibrated pipettor, add 90 μ L of Negative Control Serum and 10 μ L of sample to a separate test tube; or, alternatively, 135 μ L of Negative Control Serum and 15 μ L of sample). Mix well.
9. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:10 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
10. Read the results according to the criteria above in Test Result Appearance and Interpretation.
 - If the results are nonreactive at this dilution, the specimen should be interpreted as

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	Standard Operating Procedure	Document Number: CL08-0002 Revision: A
	CLIA Laboratory	Effective Date: 7/18/2014
Multispot HIV-1/HIV-2 Rapid Test		

“Preliminary Positive for antibodies to HIV (undifferentiated).”

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Multispot HIV-1/HIV-2 Rapid Test

- If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as Preliminary Positive for antibodies to the specific HIV type identified.
 - If one or both of the HIV-1 Spots and the HIV-2 Spot are still reactive, continue testing as follows.
11. Dilute the 1:10 diluted specimen again by 10-fold in Negative Control Serum, following the procedure in step 1 above (the final dilution is 1:100).
 12. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:100 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
 13. Read the results according to the criteria above in Test Result Appearance and Interpretation.
 - If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as Preliminary Positive for antibodies to the specific HIV type identified.
 - If the dual HIV reactivity does not disappear at the 1:100 dilution, or if the HIV-1 and HIV-2 spots both become nonreactive at the same dilution, the specimen should be interpreted as **"Preliminary Positive for antibodies to HIV (undifferentiated)."**

Follow CDC guidelines for counseling, testing, and referral when informing test subjects of these HIV test results and their interpretation.⁴²

12. LIMITATIONS OF THE PROCEDURE

1. For a preliminary positive result, when used as a rapid HIV-1/HIV-2 test, clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing (for example, Western blot or indirect immunofluorescence assay) to decide whether a diagnosis of HIV infection is accurate.
2. The Assay Procedure and the Test Result Appearance and Interpretation must be followed closely when testing for the presence of antibodies to HIV-1 or HIV-2 in plasma or serum from individual subjects. Failure to follow the procedure may give inaccurate results.
3. The test was designed to test individual specimens of fresh or frozen serum or plasma. Data regarding test kit interpretation were derived from testing individual samples. Insufficient data are available to interpret tests performed on other body specimens, pooled blood or processed plasma, and products made from such pools. Testing of these specimens is not recommended.
4. The following anticoagulants have been evaluated and found to be acceptable for use with this test: EDTA, sodium citrate, sodium heparin and SST tubes. **Use of other anticoagulants has not been evaluated and may give incorrect results.**
5. Performance of this assay has not been evaluated on patient samples that have been heat-inactivated.
6. Polystyrene tubes should not be used to prepare specimens for this test.
7. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. Testing alone cannot be used to diagnose AIDS, even if the recommended investigation of reactive specimens suggests a high probability that the antibody to HIV-1 or HIV-2 is present.
8. A nonreactive result for an individual subject indicates absence of detectable HIV antibodies. However, a nonreactive test result does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2.
9. Nonreactive results can occur if the quantity of marker present in the sample is below the detection limits of the assay, or if the marker that is detected is not present during the stage of disease in which a sample is collected.
10. The risk of any asymptomatic person with a reactive serum or plasma developing AIDS or an AIDS-related condition is not known, as the course of HIV infections may vary among individual patients and may be altered by antiretroviral therapy. However, in a prospective study, AIDS developed in 51% of homosexual men after 10 years of infection.⁴³
11. A person who has antibodies to HIV-1 is presumed to be infected with the virus, except a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.

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Multispot HIV-1/HIV-2 Rapid Test

12. Specimens which are reactive for antibodies to both HIV-1 and HIV-2 on initial testing should be retested, according to the dilutional test protocol, to identify potential cross-reaction and differentiate between HIV-1 and HIV-2. Results of dilutional testing, when used for rapid HIV-1/HIV-2 testing, should be reported as Preliminary Positive for antibodies to the specific virus type identified in the dilutional testing. Specimens that are dually reactive when tested undiluted but only reactive for one virus type at the 1:100 dilution may be dually positive; these samples are reported as Preliminary Positive for antibodies to the specific HIV type identified, when used for rapid HIV-1/HIV-2 testing.
13. The intensity of the Test Spot does not correlate with antibody titer of the specimen.
14. Samples reactive for both HIV-1 and HIV-2 may resolve to HIV-1 at higher dilutions due to the lower avidity of the HIV-2 antibody as compared to the HIV-1 antibody.
15. **The Multispot HIV-1/HIV-2 Rapid Test cannot be used as part of a diagnostic testing algorithm for both the initial testing and the differentiation testing of the same sample.**

13 – USE OF MULTISPOT AS AN ANTIBODY DIFFERENTIATION TEST IN A DIAGNOSTIC TESTING ALGORITHM

When the Multispot HIV-1/HIV-2 Rapid Test is used as an HIV-1/HIV-2 antibody differentiation assay in a diagnostic testing algorithm for HIV, as recommended by the Clinical Laboratory Standards Institute (CLSI)³², follow the previous instructions in Sections 5 – 10 and Section 12 to perform the test. The following instructions for result appearance and interpretation are used in place of the instructions in Section 11 that describe use of the assay as a rapid HIV-1/HIV-2 test.

Test Result Appearance and Interpretation – Diagnostic Testing Algorithm that Includes Differentiation between HIV-1 and HIV-2 Antibodies

Place the Cartridges with the patient ID label facing toward the operator prior to reading test results. Examine the Cartridge membrane and compare the location of colored spots to the diagram below. The appearance of a definite purple color in any of the Test Spots must be considered as presence of that Spot. Follow guidelines for using the assay in an HIV testing algorithm.³²

Multispot HIV-1/HIV-2 Rapid Test

Interpretation for Diagnostic Testing Algorithm that Differentiates HIV-1 and HIV-2 Antibodies:

Nonreactive



Label

Only the Procedural Control Spot shows purple color development. The 3 Test Spots show no color development. Test result is interpreted as negative for HIV-1 and HIV-2 antibodies. Additional testing is recommended, including HIV nucleic acid testing (NAT).

Reactive



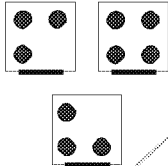
HIV-1 POSITIVE:

The Procedural Control Spot shows purple color development and **both** the recombinant HIV-1 Spot and the HIV-1 Peptide Spot show purple color development. Test result is interpreted as Positive for HIV-1 antibodies



HIV-2 POSITIVE

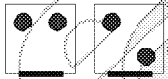
The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development. Test result is interpreted as Positive for HIV-2 antibodies



HIV POSITIVE (Undifferentiated):

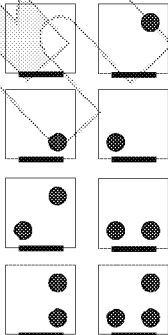
The Procedural Control Spot shows purple color development. The HIV-2 Peptide Spot shows purple color development as well as one or both HIV-1 Spots. In this case, the specimen may be tested by additional methods which allow for differentiation between HIV-1 and HIV-2. See additional procedure which follows.

Indeterminate



HIV-1 INDETERMINATE: The Procedural Control Spot shows purple color development and either the recombinant HIV-1 Spot or the HIV-1 Peptide Spot shows purple color development, but not both HIV-1 Spots. Test result is interpreted as Indeterminate for HIV-1 antibodies and testing for HIV nucleic acid is recommended.

Invalid - Do not report any results



If no color develops in the Procedural Control Spot, regardless of color development anywhere else on the membrane, the results are **INVALID**. (See examples.)

If the background on the membrane is dark and interferes with the interpretation of the spots, the results are invalid. In addition, if there are stray purple marks or discoloration that interferes with reading the spots, the assay should be repeated. Repeat the assay, and if results are still invalid collect a fresh sample or test by another method.

Note: The appearance of a definite purple color in any of the Test Spots must be considered as presence of that Spot.

Dilutional Procedure for Diagnostic Testing Algorithm that Differentiates HIV-1 and HIV-2 Antibodies

The following procedure is used to differentiate samples that demonstrate purple color development in the HIV-2 Spot as well as in one or both of the HIV-1 Spots.

1. Dilute the specimen 1:10 (using a calibrated pipettor, add 90 μ L of Negative Control Serum and 10 μ L of sample to a separate test tube; or, alternatively, 135 μ L of Negative Control Serum and 15 μ L of sample). Mix well.
2. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:10 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
3. Read the results according to the criteria below in Test Result Interpretation – Dilutional Testing for Diagnostic Testing Algorithm.

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Multispot HIV-1/HIV-2 Rapid Test


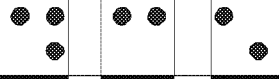

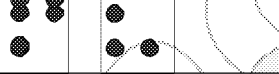
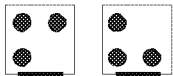
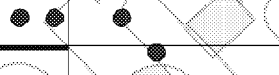

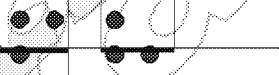



- If the Procedural Control Spot is reactive and the Test Spots are nonreactive at this dilution, the specimen should be interpreted as **“POSITIVE for antibodies to HIV (undifferentiated).”**
 - If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as POSITIVE for antibodies to the specific HIV type identified. For dilutional testing, a result is considered positive for HIV-1 if at least one of the HIV-1 spots is reactive. It is not required to have both HIV-1 spots as reactive in dilutional testing as long as both were reactive when tested undiluted. Refer to the table below for interpretation criteria.
 - If a sample is reactive for one HIV-1 spot and the HIV-2 spot on initial testing and is only reactive for the HIV-1 spot on dilutional testing, that sample should be interpreted as HIV-1 INDETERMINATE.
 - If one or both of the HIV-1 Spots and the HIV-2 Spot are still reactive, continue testing as follows.
4. Dilute the 1:10 diluted specimen again by 10-fold in Negative Control Serum, following the procedure in step 1 above (the final dilution is 1:100).
 5. Test the diluted sample as in steps 3-16 in the Assay Procedure section. Use the 1:100 diluted sample in place of the undiluted sample in step 6 of the Assay Procedure.
 6. Read the results according to the criteria below in Test Result Interpretation – Dilutional Testing for Diagnostic Testing Algorithm.
 - If the Procedural Control Spot is reactive and the Test Spots are reactive for only HIV-1 or HIV-2, the result can be reported as POSITIVE for antibodies to the specific HIV type identified. For dilutional testing, a result is considered positive for HIV-1 if at least one of the HIV-1 spots is reactive. It is not required to have both HIV-1 spots as reactive in dilutional testing as long as both were reactive when tested undiluted. Refer to the table below for interpretation criteria.
 - If the dual HIV reactivity does not disappear at the 1:100 dilution, or if the HIV-1 and HIV-2 spots both become nonreactive at the same dilution, the specimen should be interpreted as **“POSITIVE for antibodies to HIV (undifferentiated).”**
 - If a sample is reactive for one HIV-1 spot and the HIV-2 spot on initial testing and testing at a 1:10 dilution, and is only reactive for the HIV-1 spot on dilutional testing, that sample should be interpreted as HIV-1 INDETERMINATE.

Follow CDC guidelines for counseling, testing, and referral when informing test subjects of these HIV test results and their interpretation.⁴²

Multispot HIV-1/HIV-2 Rapid Test


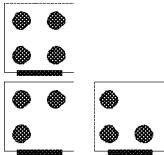
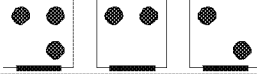

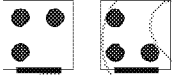


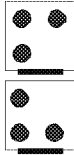
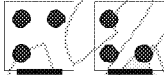
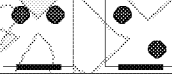

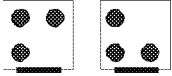

Test Result Interpretation – Dilutional Testing for Diagnostic Testing Algorithm

1:10 Dilutional testing:

Initial Result	1:10 Dilutional Result	Interpretation/Action
		HIV-1 POSITIVE
		HIV-2 POSITIVE
		Retest at 1:100 dilution
		Retest at 1:100 dilution
		HIV POSITIVE (undifferentiated)
		HIV-1 INDETERMINATE
		HIV-2 POSITIVE
		Retest at 1:100 dilution
		HIV POSITIVE (undifferentiated)

Multispot HIV-1/HIV-2 Rapid Test

1:100 Dilutional Testing:

Initial Result	1:10 Dilutional Result	1:100 Dilutional Result	Interpretation
			HIV-1 POSITIVE
			HIV-2 POSITIVE
			HIV POSITIVE (undifferentiated)
			HIV POSITIVE (undifferentiated)
			HIV POSITIVE (undifferentiated)
			HIV-1 INDETERMINATE
			HIV-2 POSITIVE
			HIV POSITIVE (undifferentiated)
			HIV POSITIVE (undifferentiated)

Multispot HIV-1/HIV-2 Rapid Test

14 BIBLIOGRAPHY

1. Centers for Disease Control: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. **Morbidity and Mortality Weekly Rep** 37:377-388, 1988.
2. Centers for Disease Control: Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. **Morbidity and Mortality Weekly Rep** 34:5-7, 1985.
3. Delmonico FL, Snyderman DR: Organ donor screening for infectious diseases. **Transplantation** 65(5):603-610, 1998.
4. Barre-Sinoussi F, Chermann JC, Rey F, et al: Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). **Science** 220:868-871, 1983.
5. Gallo RC, Salahuddin SZ, Popovic M, et al: Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. **Science** 224:500-503, 1984.
6. Coffin J, Haase A, Levy JA, et al: What to call the AIDS virus? **Nature** 321:10, 1986.
7. Clavel F, Guetard D, Brun-Vezinet F: Isolation of a new human retrovirus from West African patients with AIDS. **Science** 233:343-346, 1986.
8. Clavel F, Manshino K, Chameret S, et al: Human immunodeficiency virus type 2 infection associated with AIDS in West Africa. **New Engl J Med** 316:1180-1185, 1987.
9. Schim van der Loeff MF and Aaby P: Towards a better understanding of the epidemiology of HIV-2. **AIDS** 13 (Suppl. A): S69-S84, 1999.
10. Centers for Disease Control: AIDS due to HIV-2 infection - New Jersey. **Morbidity and Mortality Weekly Rep** 37:33-35, 1988.
11. Hoff R, Weiblen BJ, Schwerzler M, et al: Specific antibodies to HIV-2 detected in an anonymous newborn blood specimen from Massachusetts. **Fourth Consensus Conference on Testing for Human Retroviruses**, March 1989.
12. Ayanian JZ, Maguire JH, Marlink RG, et al: HIV-2 infection in the United States. **New Engl J Med** 320:1422-1423, 1989.
13. O'Brien TR, George JR, Holmberg SD: Human immunodeficiency virus type 2 infection in the United States. **JAMA** 267:2775-2779, 1992.
14. Centers for Disease Control: Update: HIV-2 infection among blood and plasma donors--United States, June 1992-June 1995. **Morbidity and Mortality Weekly Rep** 44:603-606, 1995.
15. Sullivan PS, Fleming PL: Surveillance for HIV-2 in the United States: Update and recommendations for future surveillance. Presented at the Association of Public Health Laboratories Conference, Charlotte, NC, March 6-9, 2000.
16. Brun-Vezinet F, Katlama C, Roulot D, et al: Lymphadenopathy associated virus type 2 in AIDS and AIDS-related complex. **Lancet** 1:128-132, 1987.
17. Quinn TC, Zaccarias FRK, St. John RK: AIDS in the Americas: an emerging public health crisis. **New Engl J Med** 320:1005-1007, 1989.
18. Guyader M, Emerman M, Sonigo P, et al: Genome organization and transactivation of the human immunodeficiency virus type 2. **Nature** 326:662-669, 1987.
19. Cabrian K, Shriver K, Goldstein L, et al: Human immunodeficiency virus type 2: a review. **J Clinical Immunoassay** 11:107-114, 1988.
20. Janssens W, Buvé A, Nkengasong JN: The puzzle of HIV-1 subtypes in Africa. **AIDS** 11:705-712, 1997.
21. Charneau P, Borman AM, Quillan C, et al: Isolation and envelope sequence of a highly divergent HIV-1 isolate: definition of a new HIV-1 group. **Virology** 205:247-253, 1994.
22. Simon F, Maucière P, Rogues P, et al: Identification of a new human immunodeficiency virus type 1 distinct from group M and group O. **Nature Medicine** 4:1032-1037, 1998.
23. Gao F, Yue L, Robertson DL, et al: Genetic diversity of human immunodeficiency virus type 2: evidence for distinct subtypes with differences in virus biology. **J Virology** 68:7433-7447, 1994.
24. George JR, Rayfield M, Philips S, et al: Efficacies of U.S. FDA-licensed HIV-1 screening enzyme immunoassays for detecting antibodies to HIV-2. **AIDS** 4:321-326, 1990.
25. Starcich BR, Hahn BH, Shaw GM, et al: Identification and characterization of conserved and variable regions in the envelope gene of HTLV-III/LAV, the retrovirus of AIDS. **Cell** 45:637-648, 1986.

Multispot HIV-1/HIV-2 Rapid Test

26. Wang JJG, Steel S, Wisniewolski R, Wang CY: Detection of antibodies to human T-lymphotrophic virus type III by using a synthetic peptide of 21 amino acid residues corresponding to a highly antigenic segment of gp41 envelope protein. **Proc Nat Acad Sci USA** 83:6159-6163, 1986.
27. Cosand WL: Synthetic antigen for the detection of AIDS-related disease. U.S. Patent #4,629,783, 1986.
28. Fenouillet E, Sorensen A-M, Lacroix M, Coutellier A, Herson S, Fretz-Foucault C, Gluckman J-C: Early and specific diagnosis of seropositivity to HIVs by an enzyme-linked immunosorbent assay using env-derived synthetic peptides. **AIDS** 4:1137-41, 1990.
29. Gnann JW, McCormick, Mitchell S, Nelson J, Oldstone MBA: Synthetic peptide immunoassay distinguishes HIV type 1 and HIV type 2 infections. **Science** 237:1346-1349, 1987.
30. Gnann JW, Nelson JA, Oldstone MBA: Fine mapping of an immunodominant domain in the transmembrane glycoprotein of human immunodeficiency virus. **J Virol** 61:2639-2641, 1987.
31. Alizon M, Wain-Hobson S, Montagnier L, Sonigo P: Genetic variability of the AIDS virus: nucleotide sequence analysis of two isolates from African patients. **Cell** 46:63-74, 1986.
32. Rosenberg, EC, Brennan CA, et al. Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infections; Approved Guideline Clinical and Laboratory Standards Institute, M53-A. Vol 31. No 13. 2011.
33. [HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed?term=%22Masciotra%20S%22%5BAuthor%5D"]
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34. Centers for Disease Control, Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections. **Morbidity and Mortality Weekly Report** 38(S-7): 1-7, 1989.
35. [HYPERLINK "http://www.unboundmedicine.com/medline/ebm/author/Nasrullah_M"]
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HYPERLINK "http://www.unboundmedicine.com/medline/ebm/author/Heffelfinger_JD"]
HYPERLINK "http://www.unboundmedicine.com/medline/ebm/author/Owen_SM"]JM, [
HYPERLINK "http://www.unboundmedicine.com/medline/ebm/author/Branson_BM"]BM.
Comparison of alternative interpretive criteria for the HIV-1 Western blot and results of the Multispot HIV-1/HIV-2 Rapid Test for classifying HIV-1 and HIV-2 infections. [HYPERLINK "http://www.unboundmedicine.com/medline/ebm/journal/J_Clin_Virol"]2011 Dec.;S23-S27.
36. [HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed?term=%22Styer%20LM%22%5BAuthor%5D"]
HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed?term=%22Sullivan%20TJ%22%5BAuthor%5D"]
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Multispot HIV-1/HIV-2 Rapid Test

[Evaluation of an alternative supplemental testing strategy for HIV diagnosis by retrospective analysis of clinical HIV testing data. [HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed/22018662" \l "%23"]2011 Dec;52 Suppl 1:S35-40.

37. [HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Torian%20LV%22%5BAuthor%5D"]n LV, [HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Forgione%20LA%22%5BAuthor%5D"][HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Punsalang%20AE%22%5BAuthor%5D"][HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Punsalang%20AE%22%5BAuthor%5D"]Oleszko WR. Comparison of Multispot EIA with Western blot for confirmatory serodiagnosis of HIV. [HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed/21995935" \l "%23"]2011 Dec;52 Suppl 1:S41-44.

38. [HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Wesolowski%20LG%22%5BAuthor%5D"][HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Delaney%20KP%22%5BAuthor%5D"]KP, Hart C, [HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Dawson%20C%22%5BAuthor%5D"][HYPERLINK

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"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Candal%20D%22%5BAuthor%5D"][HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Meyer%20WA%203rd%22%5BAuthor%5D"][HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Ethridge%20SF%22%5BAuthor%5D"]SF, [HYPERLINK

"http://www.ncbi.nlm.nih.gov/pubmed?term=%22Branson%20BM%22%5BAuthor%5D"]BM.

Performance of an alternative laboratory-based algorithm for diagnosis of HIV infection utilizing a third generation immunoassay, a rapid HIV-1/HIV-2 differentiation test and a DNA or RNA-based nucleic acid amplification test in persons with established HIV-1 infection and blood donors. [HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed/21995934" \l "%23"]2011 Dec;52 Suppl 1:S45-9.

39. Valkirs GE, Barton R: ImmunoConcentration™ - A new format for solid phase immunoassays. **Clin Chem.** 31: 1427-1431, 1985.40. US Department of Health and Human Services. **Biosafety in Microbiological and Biomedical Laboratories.** 5th ed. Washington, DC: US Government Printing Office, HHS publication No. (CDC) 21-1112. December 2009.41. World Health Organization. **Laboratory Biosafety Manual.** 3rd ed. Geneva: World Health Organization. 2004.42. Centers for Disease Control: Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women. **Morbidity and Mortality Weekly Rep** 50:32-35, 200143. Rutherford GW, Lifson AR, Hessel NA, et al: Course of HIV infection in a cohort of homosexual and bisexual men: an 11 year follow-up study. **Br Med J** 301: 1183-1188, 1990.44. Walther-Jallow L, Andersson S, Da Silva Z: High Concordance between Polymerase Chain Reaction and Antibody Testing of Specimens from Individuals Dually Infected with HIV Types 1 and 2 in Guinea-Bissau, West Africa. **AIDS Research and Human Retroviruses** 15: 957-962, 1999.

Multispot HIV-1/HIV-2 Rapid Test

15. REVISION HISTORY

REVISION HISTORY			
Revision Level	Effective Date	Initiator	DCO Number
A	7/18/14	G. Masinde	DCO-00023
Section Number	Description and Justification of Changes		
All	Initial Release		

theranos

Standard Operating Procedure

Document Number: SOP-75002

Revision: A


CLIA Laboratory

Effective Date: 7/18/2014

Multispot HIV-1/HIV-2 Rapid Test

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EXHIBIT 9

	Standard Operating Procedure	Document Number: CL SOP-06046 Revision: A
	CLIA Laboratory	Effective Date: 9/5/2014
Operation and Maintenance of the Siemens ADVIA Centaur XP		

Author(s):

Signature:	Date:
Name: Langly Gee	Title: QA/QC Manager

Reviewer(s):

Signature:	Date:
Name: Gurbir Sidhu	Title: Clinical Laboratory Scientist

Approver(s):

Signature:	Date:
Name: Adam Rosendorff, MD	Title: Laboratory Director


The Laboratory Director or designee will review this procedure at least annually including revisions.

Reviewed By:	Date:	Comments:

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EXHIBIT 10

	Method Validation Report - Quantitative	Document Number: CL RPT-14013
	CLIA Laboratory	Revision: A Effective Date: 05/16/2012
QUANTITATIVE METHOD VALIDATION REPORT FOR THE ABBOTT REAL TIME HIV-1 ASSAY ON THE ABBOTT DIAGNOSTICS M2000 SYSTEM		

Performed by:

Signature:	Date:
Name: Hoda Alamdar	Title: Clinical Laboratory Scientist

Author:


Signature:	Date:
Name: Suravi Thomas	Title: Laboratory Scientist

Reviewer:

Signature:	Date:
Name: Arnold B Gelb	Title: Laboratory Director

Approver:

Signature:	Date:
Name: Arnold B Gelb	Title: Laboratory Director


	Method Validation Report - Quantitative	Document Number: CL RPT-14013
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 theranos <i>redefining healthcare</i>	Method Validation Report - Quantitative CLIA Laboratory	Document Number: CL RPT-14013 Revision: A Effective Date: 05/16/2012
QUANTITATIVE METHOD VALIDATION REPORT FOR THE ABBOTT REAL TIME HIV-1 ASSAY ON THE ABBOTT DIAGNOSTICS M2000 SYSTEM		

1. Purpose

☐ Verification ☒ Validation ☐ Other:

2. Description of Test/Method

Test/Method: Abbott RealTime HIV-1

FDA Approval Status: ☒ Approved ☐ Not Approved

Location: Theranos Inc, Palo Alto, California

Date: February 21, 2012- March 14, 2012

3. Responsibilities

- a. *CLSs*: In addition to overseeing the work of the Laboratory Assistants in preparing samples, CLSs oversee the loading and running of the M2000 sp and M2000 rt.
- b. *Laboratory Assistants*: Due to the lack of manual measurements and the lack of external controls, Laboratory Assistants are able to load and operate the instrument for this Moderate Complexity CLIA Test.

4. Protocol


a. Equipment:

- Abbott Molecular M2000 sp
- Abbott Molecular M2000 rt

b. Materials:

- HIV1 Calibrator kit Lot: 435275 Exp: 3/21/2013
- HIV-1 Control kit Lot: 436849 Exp: 12/6/2012
- HIV-1 Amplification kit Lot: 436064 Exp: 1/6/2013
- Sample Prep RNA kit Lot: 10087221 Exp: 3/31/2013
- Acrometrix HIV-1 Linearity panel Lot: 201410 Exp: 02/29/2013
- Acrometrix Negative Plasma matrix Lot: 201104 Exp: 06/30/2012

c. Procedure:

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Refer to the Abbott Molecular Inc. ☐Verification/ ☒Validation Plan for M2000sp and M2000 rt Real time PCR.

d. Deviation(s) from Validation Plan (if applicable): No Deviations

e. Test Samples Required:

- 30 positive samples between ranges 1.6-7.00 Log (copies/mL)
- Negative samples
- Acrometrix HIV-1 Linearity Panel
- Acrometrix EDTA Plasma Dilution matrix

f. Testing Conditions:

- Operating temperature 15 to 30°C/59 to 86°F
- Operating humidity 30% to 80% relative (non condensing) at 30°C/86°F or below
- Operating altitude Up to 2,000 m/6,600 ft

g. Data to be collected:


- Correlation: 30 positive and 8 negative samples
- Linearity: 7 samples ranges from 0- 6.7 Log(copies/mL)
- Lower Limit of Detection: 21 replicates of 40 copies/mL; 5 replicates of 60 copies/mL, and 5 replicates of 80 copies/mL.
- Precision: 8 repeats of within run among the diluted calibrators, and between run among low and high positive and negative control.

h. Acceptance Criteria: Reaction Coefficient R2 >0.85

5. Results

All raw data reports and statistical analysis can be found in the Abbott m2000

☐Verification/ ☒Validation binder.

 theranos <i>redefining healthcare</i>	Method Validation Report - Quantitative	Document Number: CL RPT-14013
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QUANTITATIVE METHOD VALIDATION REPORT FOR THE ABBOTT REAL TIME HIV-1 ASSAY ON THE ABBOTT DIAGNOSTICS M2000 SYSTEM		

a. Precision Data- Refer to Table 1

Sample ID	log (Copies/mL)	Mean	S. D.	%CV
Cal A		3.007	0.031	1.016
	2.98			
	3			
	3.04			
Cal B		6.008	0.049	0.811
	6.09			
	6.03			
	5.98			
	5.97			
	6.02			
	5.96			

Table 1: % CV comparison Within Run.

b. Accuracy- Refer to Table 2

<u>Sample ID</u>	<u>log (Copies/mL)</u>	<u>Mean</u>	<u>S. D.</u>	<u>%CV</u>
Control L	2.97	3.067	0.067	2.171
	3.12			
	3.04			
	3.14			
	3.06			
Control H	4.99	4.971	0.045	0.909
	4.95			
	4.97			
	4.91			
	5.03			
Negative	Not detected	100 % Negative Not Detected		
	Not detected			
	Not detected			
	Not detected			
	Not detected			
	Not detected			
	Not detected			
	Not detected			


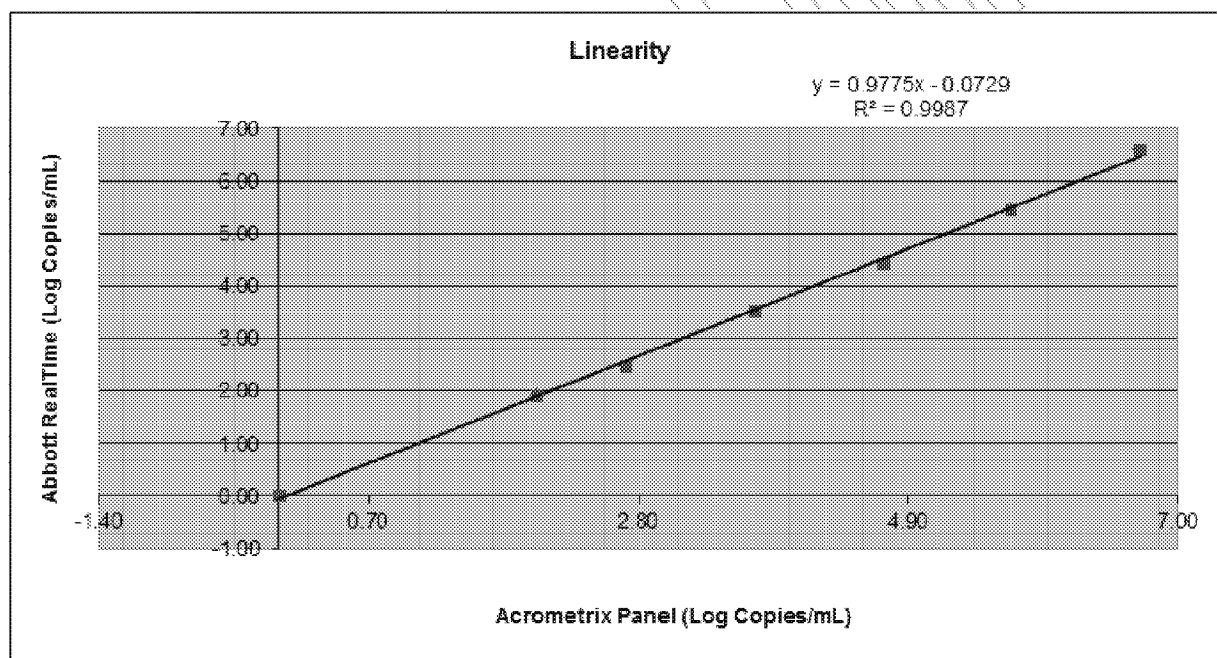
	Method Validation Report - Quantitative	Document Number: CL RPT-14013
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QUANTITATIVE METHOD VALIDATION REPORT FOR THE ABBOTT REAL TIME HIV-1 ASSAY ON THE ABBOTT DIAGNOSTICS M2000 SYSTEM		

Table 2: % CV Comparison between Low Control, High Control and Negative Control

c. Linearity and Reportable Range - Refer to Table 3a and 3b

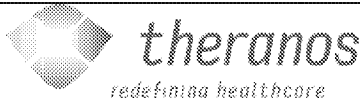
i. Linearity –

Sample ID	Acrometrix Panel Log (copies/ml)	Replicate	Abbott Real Time Log (copies/ml)
1	0.00	1	0.00
2	2.00	1	1.92
3	2.70	1	2.46
4	3.70	1	3.52
5	4.70	1	4.45
6	5.70	1	5.46
7	6.70	1	6.60

Table 3a: Acrometrix vs Abbott Real time Linearity data**Table 3b:** Linearity graph comparison between Acrometrix and Abbott real time

ii. Reportable Range: 1.6-7.0 Log (copies/mL)

d. Analytical Sensitivity (lower limit of detection)—

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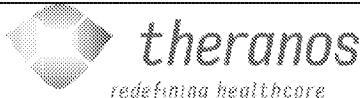
- The lower limit of detection is 40 IU/mL; 21 replicates were performed and 100% were detected (Table 4).
- Refer to test kit package insert for FDA approved tests, manufacturer's stated sensitivity: Met

<u>Sampled</u>	<u>Result Interpretation (Detected or Not Detected)</u>	<u>% Detected</u>
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	
LOD 40	Detected	100.00

Table 4a: Lower Limit of Detection

	Log copies/mL	copies/mL	
Cal A copies/mL:	2.94	871	
<u>LOD Sample</u>	<u>Cal A mL to add</u>	<u>Neg Plasma mL</u>	
40 copies/mL	1.056	21.944	21 replicates

Table 4b: Volume required for lower limit of detection

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	CLIA Laboratory	Effective Date: 05/16/2012
<p align="center">QUANTITATIVE METHOD VALIDATION REPORT FOR THE ABBOTT REAL TIME HIV-1 ASSAY ON THE ABBOTT DIAGNOSTICS M2000 SYSTEM</p>		

- e. Analytical Specificity (interfering substances) -refer to test kit package insert. For FDA approved tests, manufacturer's claims of interfering substances will be used.
- f. Reference interval(s)/Expected results - refer to test kit package insert as applicable.

6. Limitations of Procedure (if any)

N/A

7. Comments

N/A

8. References

- Abbott Real Time HIV-1 Package Insert
- Abbott Molecular M2000 Manuals sp & rt


9. Method Approval

☒ Approved for use ☐ Not Approved

If not approved, provide recommendations/corrective actions below:


10. Revision History

REVISION HISTORY			
Revision Level	Effective Date	Initiator	ECO Number
A	05/16/2012	A. Gelb	ECO-00053
Section Number	Description and Justification of Changes		
All	Initial Release		

	Method Validation Report - Quantitative	Document Number: CL RPT-14013
	CLIA Laboratory	Revision: A Effective Date: 05/16/2012
QUANTITATIVE METHOD VALIDATION REPORT FOR THE ABBOTT REAL TIME HIV-1 ASSAY ON THE ABBOTT DIAGNOSTICS M2000 SYSTEM		

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EXHIBIT 11

	Clinical Study Report Summary	Document Number: CL-RPT-15052
	CLIA Laboratory	Effective Date: 11/14/2015
Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		

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Reviewer(s)

Signature:	Date:
Name: Matthew Black, PhD	Title: Team Lead, Cytometry

Approver(s):

Signature:	Date:
Name: Sunil Dhawan, MD	Title: Laboratory Director

theranos	Clinical Study Report Summary	Document Number: CL-RPT-15052
	CLIA Laboratory	Effective Date: 11/14/2015
Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		

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theranos	Clinical Study Report Summary	Document Number: CL-RPT-15052
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Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		

1 Overview

Reliable blood cell enumeration and characterization requires rigorous evaluation of the analytic method, as well as development of quantitative acceptability limits that are used as pass/fail criteria for periodic proficiency testing. A common procedure for verifying results from a laboratory-developed test (LDT) is to compare results to an existing, routine method. In the case of the Theranos Complete Blood Count with Diff (CBC with Diff) LDT, verification is made with respect a commercial hematology analyzer often used in hospitals and independent labs.

The complexity of the CBC assay has driven the development of modern hematology analyzers that utilize various combinations of methods to characterize blood cells. These include techniques such as electrical impedance, conductivity, absorption spectrometry, and flow cytometry. Two independent research groups have recently published articles detailing comprehensive comparisons between several of the most common hematology analyzers currently in use in clinical labs (Bruegel et al. 2015; Meintker et al. 2013). Their reports demonstrate systematic differences in repeatability, specificity, and bias among the different analyzers, highlighting the importance for understanding the relationship between the test method being evaluated and the reference method.

Alternative Assessment Procedures (AAP) evaluate the agreement between the method being tested and the predicate method. A bias may exist between the methods, but the statistical significance of the bias depends on the level of measurement imprecision of the each method. This document outlines the allowable difference between the two methods, taking into consideration the imprecision and biases established in method characterization and method comparison studies. The allowable differences shall then be used as the pass/fail criteria for periodic AAP testing of the CBC with Diff LDT.

Specifically, allowed differences are provided for each measurand in the CBC with Diff assay evaluated in AAP testing, for the following method comparisons:

Theranos CBC with Diff LDT (v.1) with respect to CellDyn Ruby
 Theranos CBC with Diff LDT (v.2) with respect to CellDyn Ruby
 Theranos CBC with Diff LDT (v.2) with respect to Siemens Advia 2120i

2 Definitions

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- 2.1 **CLSI:** Clinical and Laboratory Standards Institute.
- 2.2 **Coefficient of Variation (CV):** The ratio of the standard deviation to the average, often multiplied by 100 and expressed as a percentage, abbreviated as % CV.
- 2.3 **Precision:** Precision is the closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. It is usually expressed numerically in terms of standard deviation (SD) or percent Coefficient of Variation (%CV).
- 2.4 **SOP:** Standard Operating Procedure.
- 2.5 **Test Method:** Test method encompasses the entire test procedure from blood sample collection, processing and analysis of the results.
- 2.6 **Theranos CBC with Diff LDT (v.1):** Briefly, capillary whole blood stained with fluorescently-conjugated antibodies specific for unique cell markers is analyzed on a flow cytometer to get RBC, PLT, WBC, and WBC differential. HCT is measured through image analysis of spun whole blood in a pCTN, and HGB is measured using fluorescence spectrometry.
- 2.7 **Theranos CBC with Diff LDT (v.2):** Capillary whole blood is analyzed on the Drew3 hematology analyzer to measure RBC, HCT, HGB, MCV, PLT, MPV, and WBC. The 5-part WBC differential is performed using the same Theranos chemistries and techniques as in v.1.

3 Principle

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Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		


The allowed difference (D) between two methods must account for the variance in repeatability of each of the two methods (Theranos CBC with Diff LDT and CBC with Diff on a commercial analyzer), as well as the inter-method variance. The inter-method variance can arise from method-specific biases, and from pre-analytical factors, such as sample collection. These sources of variability are encompassed in the standard deviation of the relative mean bias and mean bias estimates as defined in **CL PLN-15052 Establish Bias and Expected Difference between Methods**. The allowed difference D, between any two points, can be then be calculated. Several methods for estimating D were laid out in Equations 1, 2, 7, 9, and 10 of **CL PLN-15052 Establish Bias and Expected Difference between Methods**.

A detailed description of the relationship of intra- and inter-method variance is described in Appendix A of the CLSI guideline GP29-A2.

To evaluate AAP results, the expected Theranos value for each measurand is calculated by applying the established mean bias (or the slope and intercept). See **CL PLN-15052 Establish Bias and Expected Difference between Methods** to determine which method is appropriate.

If the difference between the expected Theranos value and the actual Theranos value for each measurand falls within $\pm D$, the results from the two methods are not considered statistically different, and are deemed passing.

4 Establishment of allowable difference for Theranos CBC with Diff LDT (v.1) with respect to Cell Dyn Ruby


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Using method comparison data in the **CL-RPT-14034 Validation Report**, slope, intercept, and mean bias were calculated for each measurand. These values were used to correct the values reported using the Theranos LDT method for WBC differential and then calculated the allowed difference, D. The standard deviation on data exhibiting a constant standard deviation, rather than a constant percent CV, at the low end of the data range was estimated and used to calculate the absolute allowed difference D by equation 10. For parameters with no expected mean bias, in which TAE was defined and used as criteria in the validation report, this TAE was used as allowed difference. For the MCH and MCHC measurands that are calculated based on values of other measurands rather than being directly measured, the inter-method CV is defined as the square root of the sum of the squares of the difference allowed for the parameters used in the calculation as in Equation 9. Results are show in Table 1 below.

Measurand	Allowed Difference, D (%)	Allowed Difference D, Absolute	Slope	Intercept	Units	Equation used to calculate D
NEUper	5.0	0.3	1.013	0	%	7
LYMper	9.8	0.3	0.99	0	%	7
MONOper	26	0.3	0.90	0	%	7
EOSper	28	0.3	1.03	0	%	7
BASOper	58	0.3	0.782	0	%	7
HCT	6	0	1	0	%	1
HGB	7	0	1	0	g/dL	1
MCH	9.2	0	1	0	pg	9
MCHC	10.5	0	1	0	g/dL	9
MCV	5	0	1	0	fL	1
MPV	25	0	0.51	3.99	fL	1
PLT	25	5.4	1	0	10 ³ /uL	1
RBC	6	0	1	0	10 ⁶ /uL	1
RDW	5	0	0.64	4.30	%	1
WBC	15	0.3	1	0	10 ³ /uL	1

Table 1. Slope, intercept, and D for each measurand reported in the Theranos CBC with Diff LDT. Calculations made using data from CL-RPT-14034.

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Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		

5 Establishment of allowable difference for Theranos CBC with Diff LDT (v.2) with respect to CellDyn Ruby

Using method comparison data in the **CL-RPT-14028 Verification Report for Drew3 for Complete Blood Count**, slope, intercept, and mean bias were calculated for the measurands reported for Drew3. The WBC differential values remained unchanged from those calculated for allowable difference for Theranos CBC with Diff (v.1) with respect to CellDyn Ruby. These values were used to correct the values reported using the Theranos LDT method for WBC differential and then calculated the allowed difference, D. The standard deviation on data exhibiting a constant standard deviation, rather than a constant percent CV, at the low end of the data range was estimated and used to calculate the absolute allowed difference D by equation 10. For the MCH and MCHC measurands that are calculated based on values of other measurands rather than being directly measured the inter-method CV is defined as the square root of the sum of the squares of the difference allowed for the parameters used in the calculation as in Equation 9. Results are shown in Table 2 below.

Measurand	Allowed Difference, D (%)	Allowed Difference D, Absolute	Slope	Intercept	Units	Equation used to calculate D
NEUper	5	0.3	1.013	0	%	7
LYMper	9.8	0.3	0.99	0	%	7
MONOper	26	0.3	0.9	0	%	7
EOSper	28	0.3	1.03	0	%	7
BASOper	58	0.3	0.782	0	%	7
HCT	6	0	1	0	%	1
HGB	7	0	1	0	g/dL	1
MCH	9.2	0	1	0	pg	9
MCHC	10.1	0	1	0	g/dL	9
MCV	4	0	1	0	fL	7
MPV	17.6	0	0.41	6.41	fL	7
PLT	25	5.4	1	0	10 ³ /uL	1
RBC	6	0	1	0	10 ⁶ /uL	1
RDW	15	0	1	0	%	1
WBC	15.76	0.3	1	0	10 ³ /uL	7

Table 2. Slope, intercept, and D for each measurand reported in the Theranos CBC with Diff LDT.

6 Establishment of allowable difference for Theranos CBC with Diff LDT (v.2) with

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Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		

respect to Siemens Advia 2120i

Using method comparison data in Appendix A, slope, intercept, and relative mean bias were calculated for the measurands reported for Theranos LDT v.2 in comparison to Siemens Advia 2120i. These values were used to correct the values reported using the Theranos LDT method (v.2) for all measurands and then calculated the allowed difference, D. The standard deviation on data exhibiting a constant standard deviation, rather than a constant percent CV, at the low end of the data range was estimated and used to calculate the absolute allowed difference D by equation 10. For the MCH, and MCHC measurands that are calculated based on values of other measurands rather than being directly measured the inter-method CV is defined as the square root of the sum of the squares of the difference allowed for the parameters used in the calculation as in Equation 9. Results are show in Table 3 below.

Measurand	Allowed Difference, D (%)	Allowed Difference D, Absolute	Slope	Intercept	Units	Equation used to calculate D
NEUper	8.40	0.30	1.018	0	%	7
LYMper	14.20	0.30	0.942	0	%	7
MONOper	22.10	0.30	1.16	0	%	7
EOSper	52.70	0.53	0.81	0	%	7
BASOper	70.80	0.85	1.06	0	%	7
HCT	8.40	0.00	1	0	%	2
HGB	7.34	0.00	1	0	g/dL	7
MCH	10.57	0.00	1	0	pg	9
MCHC	11.40	0.00	1	0	g/dL	9
MCV	4.29	0.00	1	0	fL	7
MPV	21.90	0.00	0.89	2.02	fL	7
PLT	24.60	5.40	1	0	10 ³ /uL	7
RBC	7.60	0.00	1	0	10 ⁶ /uL	7
RDW	27.60	0.00	1.88	-12.61	%	7
WBC	18.40	0.30	1	0	10 ³ /uL	7

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Establishing allowable difference between Theranos lab-developed hematology tests and commercial hematology analyzers		

Table 3. Slope, intercept, and D for each measurand reported in the Theranos CBC with Diff LDT (v.2). Advia 2120i. Calculations made using data from Appendix A.

7 REFERENCES

- 7.1 CLSI Guideline GP 29 Assessment of laboratory tests when proficiency testing is not available; approved guideline, second edition
- 7.2 Bruegel, M., Nagel, D., Funk, M., Fuhrmann, P., Zander, J., Teupser, D. Comparison of five automated hematology analyzers in a university hospital setting: Abbott Cell-Dyn Sapphire, Beckman Coulter DxH 800, Siemens Advia 2120i, Sysmex XE-5000, and Sysmex XN-2000. Clin. Chem. Lab. Med. 2015; 53(7).
- 7.3 Meintker, L., Ringwald, J., Rauh, M., Krause, S. Comparison of automated differential blood cell counts from Abbott Sapphire, Siemens Advia 120, Beckman Coulter DxH 800, and Sysmex XE-2100 in normal and pathologic samples. Am. J. Clin. Pathol. 2013; 139:641-650.

8 REVISION HISTORY

REVISION HISTORY			
Revision Level	Effective Date	Initiator	DCO Number
A	11/14/2015	A.Trent	DCO-00108
Section Number	Description and Justification of Changes		
All	Initial Release		

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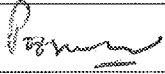
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EXHIBIT 12

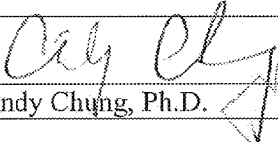
theranos	Test Plan	Document Number: CL PLN-14220 Revision: A
	Product Development	Effective Date: 11/14/15
Verification Plan for DREW3, an Automated Hematology Analyzer		

Verification Plan for DREW3, an Automated Hematology Analyzer

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1.0 PURPOSE:

- 1.1 The purpose of this test plan is to define the experiments and selection criteria for verification of Complete Blood Count (CBC) within the CLIA infrastructure, using DREW3, an automated hematology analyzer. This document outlines the types and order of experiments necessary to complete an assessment of substantial equivalence following the latest CLSI guidelines.

2.0 SCOPE:

- 2.1 This plan applies to running DREW3, an automated hematology analyzer FDA 510(k) cleared methodology per CLSI recommendation in Theranos clinical laboratory.

3.0 BACKGROUND:

- 3.1 Reason for the Study:

- 3.1.1 This plan outlines the standardized set of experiments necessary to verify CBC assay on DREW3.
- 3.1.2 The following experiments were done to verify DREW3 510K approved pass/fail criteria and test ranges:
- 3.1.2.1 Verification of the Limit of Blank (CLSI EP17-A2E)
 - 3.1.2.2 Verification of Linear Range (CLSI EP06-AE).
 - 3.1.2.3 Verification of Precision (vendor recommendation)
 - 3.1.2.4 Establish comparability: Method Comparison with Capillary Plasma (CLSI EP05-A3)
 - 3.1.2.5 Establishment of Reference Interval Limits for capillary samples (EP28-A3CS)

4.0 DEFINITIONS:

- 4.1 **Accuracy:** Accuracy is defined by CLSI as the closeness of agreement between a test result and an accepted reference value. Method accuracy is used in a different sense by the American Association of Pharmaceutical Scientists where it is expressed as percent relative error (%RE). Trueness, a related CLSI term, is the closeness of agreement between the average of a number of replicate measured quantity values and a reference quantity value.
- 4.2 **Analyte:** Component represented in the name of a measurable quantity. The closely related term measurand is defined as the particular quantity subject to measurement.
- 4.3 **Analytical sensitivity:** There are several alternative uses of this term. Most commonly, and for the purposes of this Validation Plan, it is used interchangeably with limit of detection. It is also used to describe the ability of an analytical method to assess small variations of the concentration of an analyte, such as the slope of the calibration curve (IUPAC).

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- 4.4 **Analytical specificity:** Ability of a test or procedure to correctly identify or quantify an entity, including in the presence of interfering substance(s) or phenomena.
- 4.5 **Calibration:** Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. Under CLIA, calibration refers to the process of testing and adjusting an instrument, kit, or test system, to provide a known relationship between the measurement response and the value of the substance being measured by the test procedure (42 CFR 493.1217).
- 4.6 **Calibrator:** A substance, material, or article intended to be used to establish the measurement relationships of a diagnostic medical device.
- 4.7 **CLIA:** Clinical Laboratory Improvement Amendments of 1988. Congressional legislation that defined and requires specific quality assurance practices in clinical laboratories.
- 4.8 **CLSI:** Clinical and Laboratory Standards Institute.
- 4.9 **Coefficient of Variation:** The ratio of the standard deviation to the average, often multiplied by 100 and expressed as a percentage, abbreviated as % CV.
- 4.10 **Colorimetry:** A technique used to determine the concentration of colored compound(s) in solution.
- 4.11 **Interfering substance:** A substance or quantity thereof that is not the measurand but that affects the result of the measurement.
- 4.12 **IUPAC:** International Union of Pure and Applied Chemistry
- 4.13 **Linearity:** Linearity is the ability of a quantitative analytical method to provide results that are directly proportional to the concentrations of an analyte in test samples, within a given measuring interval. It is an important parameter to confirm when evaluating an analytical method because it verifies correct interpolation of results between points.
- 4.14 **LMR:** Lower end of the measuring range is the lowest level at which defined conditions, including all stated characteristic of the method, are met.
- 4.15 **LoB:** Limit of Blank is the highest value in a series of results on a sample that contains no analyte.
- 4.16 **LoD:** Limit of Detection is the lowest amount of analyte in a sample that can be detected with stated probability, although perhaps not quantified as an exact value.
- 4.17 **Matrix:** All components of a material system, except the analyte. A specimen matrix is the biological milieu in which an analyte exists (e.g., plasma, serum, urine, or other body fluids).
- 4.18 **Measuring Interval (reportable range; analytical measurement range or AMR):** A measuring interval consists of all numeric values between the lower and upper numeric values for which a method can produce quantitative results suitable for clinical use. Where applicable, a linearity study is frequently used to establish or verify the measuring interval that can be reported for a measurement method. Alternatively, the lower limit of the measuring interval may be assigned as the limit of quantification (LLOQ).
- 4.19 **Precision:** Precision is the closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. It is usually expressed numerically in terms of standard deviation (SD) or percent Coefficient of Variation (%CV).

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- 4.20 **Reference interval:** The interval between and including two reference limits. It is common practice to define a reference limit so a stated fraction of the reference values is less than or equal, or greater than or equal, to the respective upper or lower limit.
- 4.21 **SOP:** Standard Operating Procedure.
- 4.22 **Testing System:** The entirety of the testing process, including instrument, sample, reagents, supplies, and procedures. Personnel are sometimes included in the definition.

5.0 RESPONSIBILITY:

- 5.1.1 It is the responsibility of the Laboratory Director to ensure that the verification experiments ran on DREW3 in Theranos clinical laboratory pass the testing criteria as claimed in the manufacturer's FDA 510K report.
- 5.1.2 It is the responsibility of all Testing Personnel in the CLIA laboratory to follow the steps indicated in this verification plan and associated SOPs.

6.0 TESTING SYSTEMS:

- 6.1 The testing system defined for this validation plan is the DREW3, an automated hematology analyzer

7.0 PROCEDURES:

- 7.1 Limit of Blank, Detection and Quantitation
- 7.1.1 Limit of Blank (LoB) will be verified with DI water with a minimum of 10 replicates. DI water will be run on DREW3 and data was analyzed according the CLSI documentation
- 7.1.2 Selection Criteria: LoB values should be below the linearity reported in the 510K.
- 7.2 Verification of Linear Range
- 7.2.1 Establishment of the Linear Range is performed using contrived samples for RBC, HGB, PLT and WBC. A minimum of 5 levels performed in 3 replicates spanning the analytical range of the assay is necessary to establish the linear range. Data will then be retrieved and inputted into Statist Pro for analysis.
- 7.2.2 Selection Criteria: Linearity will be established, according CLSI EP06-AE, with an allowable non-linearity of <10%.
- 7.3 Verification of Precision
- 7.3.1 Verification of precision is performed as per vendor's recommendation to run 3 blood samples 10 times. The data will then be retrieved and compared to the vendors 510 k submission.
- 7.3.2 Selection Criteria: Precision is verified according to the comparison of estimated repeatability to manufacturer's claims as outlined in CLSI EP15-A2.
- Within-laboratory precision for each analyte is to be used in the calculation of allowable bias for trueness and comparability testing. This data is to be used to populate for this calculation where SD is the standard deviation of the precision data set at the lowest concentration and MEAN is the average measured value of the precision data set at the lowest concentration.

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7.4 Establishment of Comparability: Method Comparison with Capillary Plasma

7.4.1 Establishment of comparability serves to draw the comparison between capillary sample processing on DREW3 when compared to a venous sampling from the same donor as a predicate. This study is also a matrix study, comparing venous and capillary plasma. Guidance is taken from CLSI H26-A2. A minimum of 40 unique samples spanning the physiological range are to be tested on DREW3 system. From each unique donor, up to 2 Theranos Sample Collecting Devices of the EDTA anticoagulant type will be collected simultaneously with 1 EDTA BD vacutainer for CBC. All blood collection is to be carried according to manufacturer intended use or current operating protocol. Samples are to be processed according CL-SOP-15051. In addition to the unique patient samples, contrived samples are to be generated to span the medical decision limit ranges. The number of contrived samples is not to exceed 15% of the total patient samples in this study. Contrived samples are generated by manipulated venous whole blood. Donor matched plasma is either added or removed to whole blood aliquots to achieve the specified concentration targets. For platelet (PLT) and white blood cell (WBC), platelet rich plasma or isolated WBCs are spiked into a known concentration of analyte in a venous plasma to achieve the specified concentration targets. Contrived samples are then aliquoted into a Theranos sample containing unit and the appropriate containers for the comparative measurement system. The Theranos sample should be processed according to CL-SOP-15086 and the appropriate protocol followed for the comparative measurement procedure.

7.4.2 Selection Criteria: Verification of trueness is defined as the mean bias and 95% confidence interval of the mean bias within the total allowable bias calculated using Table 1.

7.5 Establishment of Analyte Stability

7.5.1 Establishment of analyte stability is to be performed if the testing protocol deviates from the manufacturer's intended stability. A minimum of 20 unique donors is to be used to establish extended analyte stability. Two (2) Theranos sample collecting devices are to be drawn from each donor. Samples were processed at 1-4 hours (T0) and 32-36 hours (T36) post collection according to CL-SOP-15086, and assay results will be compared between the initial processing time (T0) and after sample storage at 2-8°C for 36 hours (T36).

7.5.2 Selection Criteria: Mean bias and its 95% confidence interval at T36 must be within the allowable bias specified for each analyte.

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7.6 Establishment of Reference Interval with Capillary samples

7.6.1 Establishment of the reference interval is to be performed using a minimum of 100 unique, donors from an apparently healthy reference population. The reference population is to be composed of male and female donors from three unique Theranos Collection Sites: Palo Alto, Newark, and Scottsdale. Two (2) Theranos sample collecting devices are to be drawn from the patients in the reference population. These capillary blood specimens are to be transported to the Theranos clinical laboratory for processing within 24 hours of collection. All samples are to be processed according to CL-SOP-15086 within 36 hours of specimen collection. Data is to be retrieved from Theranos LAS and input into Statistix Pro for determine of the reference interval and 95% confidence intervals on the reference limits. Symmetrical robust statistical methods should be applied to this data unless the data set exceeds N = 120 in which case non-robust parametric statistical may be accurately applied.

7.6.2 Selection Criteria: The reference interval limits and the corresponding 95% confidence interval of those limits must be comparable to the corresponding venous reference interval determined within the same device. Deviations from these limits may indicate a difference in the clinical performance of capillary blood, and the reference range should be verified or established accordingly.

8.0 ACCEPTANCE CRITERIA, SAMPLE SIZE AND TEST CONDITIONS:

8.1 Acceptance Criteria and Justifications:

Acceptance criteria, allowable bias, for Method Comparison studies is detailed in Table 1.

Table 1: Acceptance Criteria for venous and capillary measurements

Assay	Sample	TAE (%)	TAE (abs)	Imprecision CV (%) 510k	Allowable Bias (%)
WBC	Venous	15		2.0	TAE (%) – (2 x CV)
RBC	Venous	6		1.0	TAE (%) – (2 x CV)
HGB	Venous	7		0.6	TAE (%) – (2 x CV)
HCT	Venous	6		1.0	TAE (%) – (2 x CV)
MCV	Venous	25		0.4	TAE (%) – (2 x CV)
RDW	Venous	5		3.3	TAE (%) – (2 x CV)
PLT	Venous	15		3.6	TAE (%) – (2 x CV)
MPV	Venous	9		1.2	TAE (%) – (2 x CV)
WBC	Capillary	15		2.0	TAE (%) – (2 x CV)
RBC	Capillary	6		1.0	TAE (%) – (2 x CV)
HGB	Capillary	7		0.6	TAE (%) – (2 x CV)
HCT	Capillary	6		1.0	TAE (%) – (2 x CV)
MCV	Capillary	25		0.4	TAE (%) – (2 x CV)
RDW	Capillary	5		3.3	TAE (%) – (2 x CV)
PLT	Capillary	15		3.6	TAE (%) – (2 x CV)

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MPV	Capillary	9	1.2	TAE (%) – (2 x CV)
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9.0 REFERENCES

- 9.1 CLSI EP06-AE, Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline, 2003, Clinical and Laboratory Standards Institute, Wayne, PA.
- 9.2 CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline- Third Edition, 2014, Clinical and Laboratory Standards Institute, Wayne, PA.
- 9.3 CLSI EP28-A3CS, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition, 2010, Clinical and Laboratory Standards Institute, Wayne, PA.
- 9.4 CLSI EP17-A2E, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, 2012, Clinical and Laboratory Standards Institute, Wayne, PA.
- 9.5 CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, 2013, Clinical and Laboratory Standards Institute, Wayne, PA.
- 9.6 H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition, 2010, Clinical and Laboratory Standards Institute, Wayne, PA.
- 9.7 StatPro (version 1.13.00), Clinical and Laboratory Standards Institute, Wayne, PA. 07/14/2011.

10.0 APPENDICES

10.1 N/A

Revision History			
Revision Level	Effective Date	Initiator	DCO Number
A	11/14/2015	P.Kolhar	DCO-00108
Section Number	Description and Justification of Changes		
All	Initial Release		

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theranos	Test Plan	Document Number: CL PLN-14220
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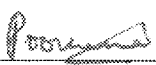
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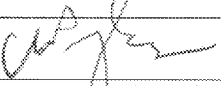
theranos	Commercial System Verification Report	Verification of Drew 3 for Complete Blood Count	Rev:
			A
Description	Verification of Drew 3 for Complete Blood Count		
Originator: Poornima Kolhar	Date: 08/30/2014		Page 1 of 12

Verification of Drew 3 for Complete Blood Count

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theranos	Commercial System Verification Report	Verification of Drew 3 for Complete Blood Count	Rev:
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Description	Verification of Drew 3 for Complete Blood Count		
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Verification of Drew 3 for Complete Blood Count

1. Overview
2. Principle
3. Method Characterization
 - a. Precision
 - b. Establishing the Analytical Measurement Interval or Linearity
 - c. Limit of Blank and Carryover
4. Method Comparison
 - a. Accuracy or Comparability with Predicate
5. Sample Stability

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1. Overview

The clinical value of the Complete Blood Count has been demonstrated as a fundamental diagnostic and monitoring tool for a broad spectrum of pathologies in numerous studies. In the clinical laboratory, manual counts using hemocytometer and a light microscope have been largely replaced by automated flow based devices that use impedance or optical methods for cell detection (Greer, 2008). One such device is the Drew-3 an automated hematology analyzer. In this document we verify the use of Drew-3 to run samples and verify their linearity, LOB, LOD and LOQ data.

The CBC with Leukocyte Differential and Reticulocytes assay is broken up into the analysis of Red Blood Cells (RBCs), Platelets (PLTs), White Blood Cells (WBCs), and assays that measure the cellular properties of these cells. The assays that measure RBCs are the RBC count assay, the Hemoglobin Assay (HGB), and the Hematocrit assay (HCT). The properties of RBCs that are assayed consists of the Mean Corpuscular Volume (MCV) of RBCs, the Mean Corpuscular Hemoglobin (MCH), the Mean Corpuscular Hemoglobin Concentration (MCHC), and the Red Blood Cell Distribution Width (RDW). The assays that measure Platelets are the Platelet Count assay (PLT) and the Mean Platelet Volume assay (MPV). The assays that measure White Blood Cells are the WBC count. The Leukocyte Differential which reports the percentage of the White Blood Cells that are comprised of Neutrophils (NEUT), Lymphocytes (LYMPH), Monocytes (MONO), Eosinophils (EOS), and Basophils (BASO) will be determined by the previously established Normandy.

The clinical value of red blood cell (RBC; erythrocyte) counts and platelet counts have been demonstrated as a fundamental diagnostic and monitoring tool for a broad spectrum of pathologies in numerous studies. In the clinical laboratory, manual counts using hemocytometer and a light microscope have been largely replaced by automated flow based devices that use impedance, fluorescence, and optical methods for cell detection.

The clinical value of leukocyte count and differential has been demonstrated in numerous studies. Current state of the art is dominated by class of devices called Automated Hematology Analyzers which classify leukocytes based on their physical properties such as size, granularity, absorbance etc. which have been historically validated for normal samples. This, combined with a coulter-principle based counting mechanism allows for rapid processing of samples.

In addition to the counting of RBCs, the properties of the erythrocyte fraction of blood are important for diagnostics as well. The blood hemoglobin (HGB) concentration is a well-established absorbance-based assay with demonstrated clinical value, as are the Hematocrit (HCT)

The properties of the erythrocytes themselves are also important diagnostic tools. Mean corpuscular volume (MCV) is the average volume of individual red blood cells (RBCs), and the red cell distribution width (RDW) is the coefficient of variance of that volume. These values are used along with hematocrit and hemoglobin levels to determine the presence, type and magnitude of anemia. MCV and RDW are commonly included on the complete blood count (CBC) panel of lab tests.

Also part of the CBC is the mean platelet volume (MPV). Platelets are formed in the bone marrow by budding off of megakaryocytes. MPV is used in combination with the overall platelet count as indicators of blood and bone marrow conditions.

The Drew-3 analyzer is a device that uses a combination of impedance, and optical methodologies to quantify all of the assays listed above from Whole Blood (WB) samples except the WBC diff which will be outlined in the previous Theranos LDT

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2. Principle

In this method, RBC, HGB, HCT, RET, MCV, MCH, MCHC, RDW, PLT, MPV and WBC are measured using impedance and optical measurements of the cells. Whole blood (from either Venous or Finger Stick sources) is run directly on the device. The data is validated against the blood run on Cell-Dyn Ruby system.

3. Method Characterization

a. Precision:

CLSI standard EP05-A2 defines precision as the closeness of agreement between independent test/measurement results obtained under stipulated conditions. The term stipulated conditions encompasses a wide variety of contexts encountered in the process of clinical analysis. For the purpose of this validation study, precision was measured and characterized in the context of within run precision. The main objective behind characterization of precision under the above condition is to demonstrate that this method is robust to the different sources of variation inherent in the analytical method.

Thirty-one replicates of the same sample were analyzed on the Drew-3 in pre-dilute mode for three different donors. The coefficient of variation across these replicates characterizes the within run precision for this method (Table 1).

Drew-1	Donor 1		Donor 2		Donor 3		Donor 4	
No of replicates	12		12		12		12	
Assay	Value	CV(%)	Value	CV(%)	Value	CV(%)	Value	CV(%)
WBC ($10^3/\text{ul}$)	7.14	0.94	4.97	1.98	4.65	1.72	7.36	1.69
RBC ($10^6/\text{ul}$)	4.94	0.62	4.68	0.70	4.87	0.82	4.62	0.98
HGB (d/dL)	15.78	0.48	13.99	0.48	14.93	0.44	14.48	0.58
HCT(%)	46.69	0.66	42.08	0.78	43.93	0.78	42.53	1.13
MCV(fL)	94.44	0.39	90	0.58	90.19	0.48	92.04	0.50
MCH(pg)	31.92	0.44	29.93	0.64	30.68	0.78	31.35	0.97
MCHC(g/dL)	33.78	0.59	33.26	0.81	33.99	0.82	34.07	1.26
RDW(%)	10.94	2.93	10.88	2.74	10.33	2.96	11.1	2.66
PLT($10^3/\text{ul}$)	178.67	5.15	213.58	2.04	282.92	3.36	281.08	2.64
MPV(fL)	8.77	1.56	8.53	2.02	8.16	1.43	7.75	2.37

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Drew-2	Donor 1		Donor 2		Donor 3		Donor 4	
No of replicates	12		12		12		12	
Assay	Value	CV(%)	Value	CV(%)	Value	CV(%)	Value	CV(%)
WBC (10 ³ /ul)	7.17	1.26	5.17	1.51	4.80	2.35	7.39	1.68
RBC (10 ⁶ /ul)	4.95	0.55	4.73	0.82	4.95	0.79	4.71	0.34
HGB (d/dL)	15.63	0.30	13.88	0.33	14.88	0.39	14.44	0.69
HCT(%)	45.68	0.29	41.67	0.83	43.78	0.89	42.43	0.50
MCV(fL)	92.29	0.34	88.01	0.47	88.41	0.48	90.03	0.44
MCH(pg)	31.58	0.51	29.32	0.83	30.04	0.86	30.63	0.55
MCHC(g/dL)	34.22	0.43	33.31	0.85	34.00	1.08	34.03	0.75
RDW(%)	12.73	2.63	13.18	2.76	12.40	3.15	13.53	2.38
PLT(10 ³ /ul)	190.55	2.55	234.25	2.77	305.58	2.44	294.67	2.88
MPV(fL)	9.70	2.48	9.32	2.28	8.94	1.39	8.48	1.60

Table 1: Precision for 12 replicates for 4 donors run on 2 separate days in pre-dilute mode for all reportable assays.

b. Establishing the Analytical Measurement Interval or Linearity

CLSI guidance document H26AE defines the analytical measurement interval or analytical measurement range as the range of analytical values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. The aim of this part of the validation program was to establish an analytical measurement range significantly wider than the typical clinically reportable interval. In effect, this implies that the said method will provide sensible results, without dilution further than the established protocol, or any other pretreatment such as concentration for any sample which the laboratory wishes to analyze. To this end, fresh whole blood samples were diluted to yield a range of concentrations for the RBC, HGB, HCT, PLT, and WBC that is significantly wider than any expected physiological range. The MCV, RDW, and MPV assays do not rely on concentration measurements beyond the minimal concentration required to obtain the result, and thus linearity for those assays is not necessary and not included in this section of the report. Graphical representation and regression statistics for each assay dataset are shown in the following figure (Figure 1). The goodness of fit establishes the "linearity" or the analytical measurement interval for this assay over the specified ranges in Table 3, and the statistical parameters for these data are shown in Table 4. Confirmation of the linearity range of Drew 3 as filed in the 510k.

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Assay	Range
RBC($10^6/\mu\text{L}$)	0.36-7.13
HGB(g/dL)	0.1 – 20.5
HCT(%)	0.5-60.5
PLT($10^3/\mu\text{L}$)	11- 750
WBC($10^3/\mu\text{L}$)	0.74-88.2

Table 3: Linearity ranges for the RBC, HGB, HCT, PLT, and WBC

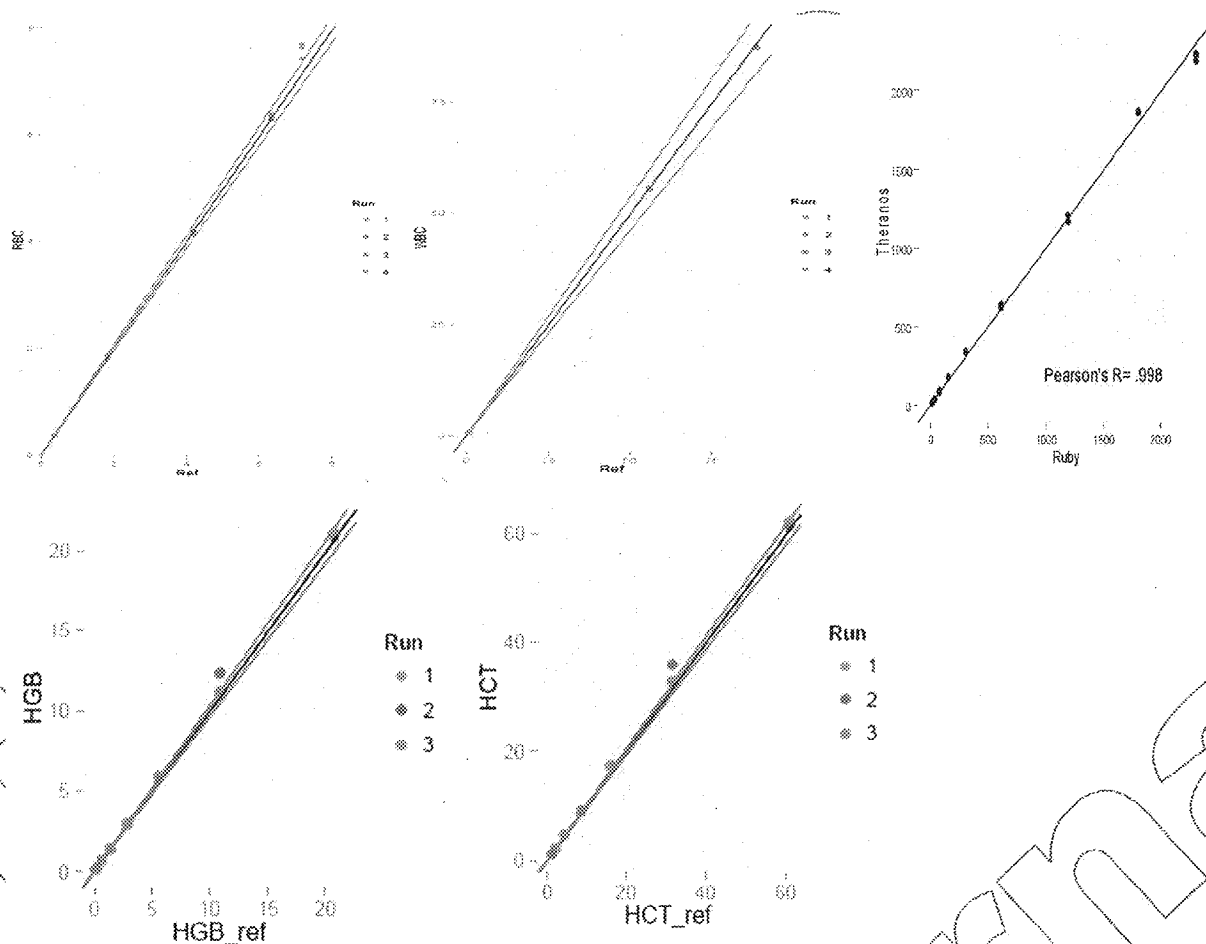


Figure 1 Concordance between Drew3 and Ruby Whole Blood measurements showing linearity over the analytical range.

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c. Limit of blank (LoB)

Whole blood samples with high RBC, PLT, and WBC concentrations were run alternately with blank samples to quantify the limit of blank with carryover (Table 5).

Assay	Limit of blank, With carryover	Limit of blank, with carryover, as % of concentration of prior sample (%)
RBC	0.00 ± 0.00 ($10^6/\mu\text{L}$)	0.00 ± 0.00 %
HGB	0.00 ± 0.00 (g/dL)	0.00 ± 0.00 %
RET	0.00 ± 0.00 ($10^6/\mu\text{L}$)	0.00 ± 0.00 %
PLT	0.00 ± 0.00 ($10^3/\mu\text{L}$)	0.00 ± 0.00 %
WBC	0.00 ± 0.000 ($10^3/\mu\text{L}$)	0.1 ± 0.1 %

Table 5: Limit of blank with carryover.

4. Method Comparison

a. Accuracy or Comparability with Predicate

In this section, data showing the comparability or accuracy of the Theranos assay on Drew with assay on Ruby. Following figures and table show the comparison between the Theranos assay and reference on Ruby.

Table 6 :Method comparison

	Assay	Mean Recovery	Mean CV
1	WBC	1.00	3.311221
2	RBC	1.00	1.19404
3	HGB	1.00	0.842274
4	HCT	1.00	1.175537
5	PLT	1.00	6.661374
6	MCV	1.00	0.954951
7	RDW	1.00	4.191514
8	MCH	1.00	0.981301
9	MCHC	1.00	1.110792
10	MPV	0.98	10.39399

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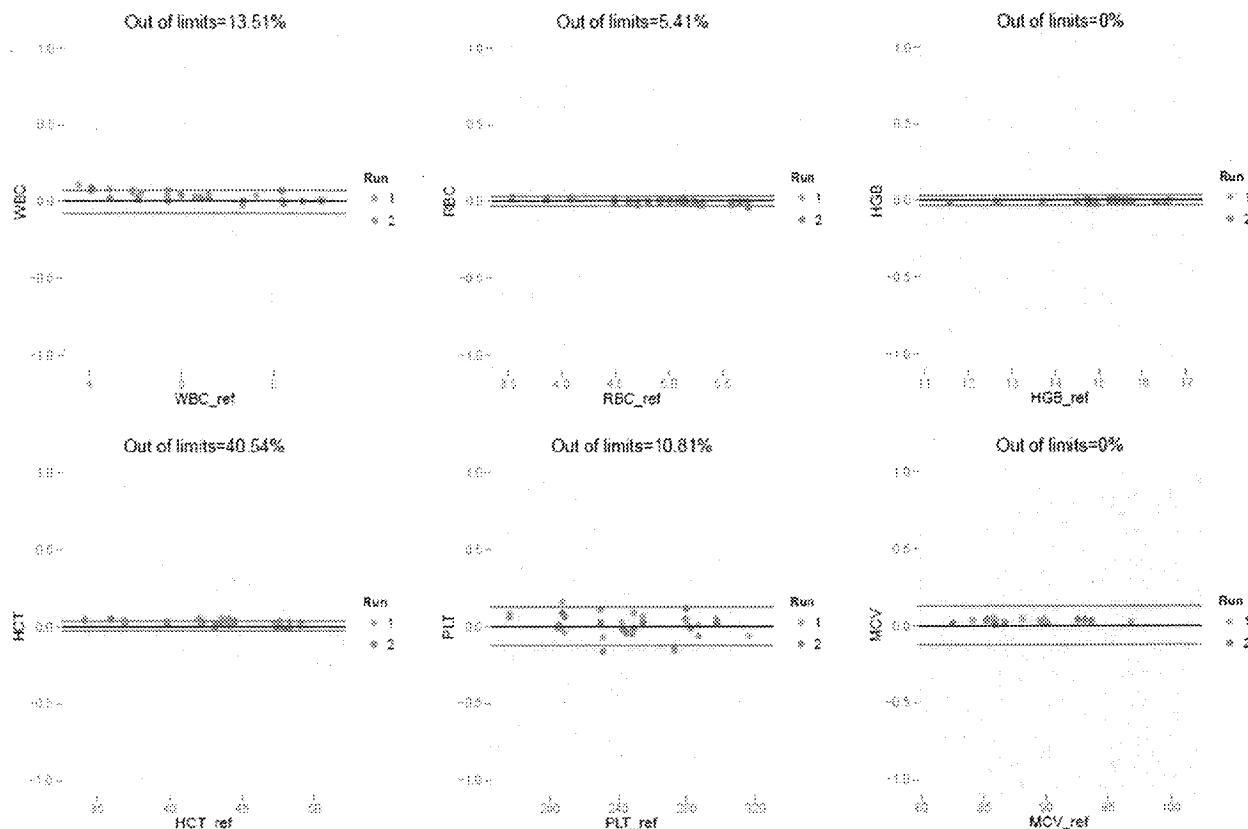


Figure 2a: Method comparison between Drew and Ruby

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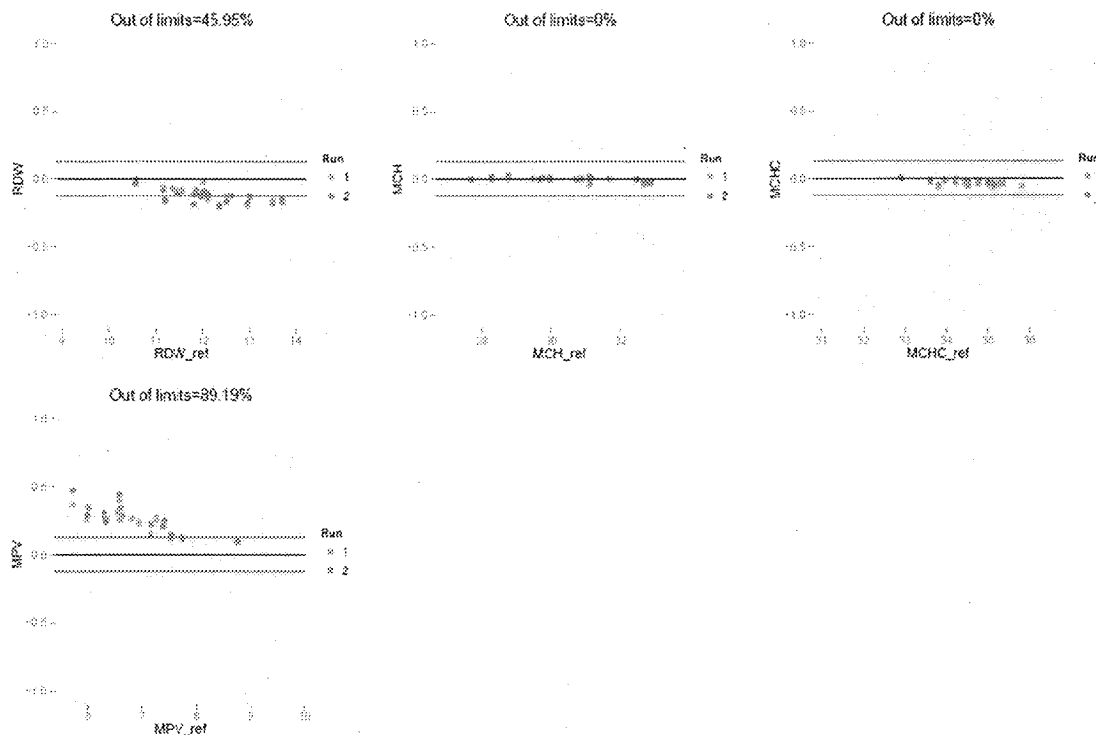


Figure 2b : Method comparison between Drew and Ruby

5. Sample Stability

Sample stability was assessed at time 4h and 36h on Drew. pCTNs were stored at 4C before they were run on Drew. Following are the results from the stability studies which showed that the analytes can be measured even at 36 h and are within the allowed TAE

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	Assay	MeanRecovery	CV
1	WBC	1.012457	8.531075
2	RBC	0.995051	4.303214
3	HGB	0.994414	3.448158
4	HCT	0.993858	4.405814
5	PLT	0.963501	8.058931
6	MCV	0.998451	0.646994
7	RDW	1.003001	3.938081
8	MCH	1.006509	1.734351
9	MCHC	1.007849	2.206195
10	MPV	1.012133	3.705816
11	MON	0.950615	25.92279
12	LYM	1.0657	8.660984

Table 6 : Table shows recovery at 36 h for pCTNs

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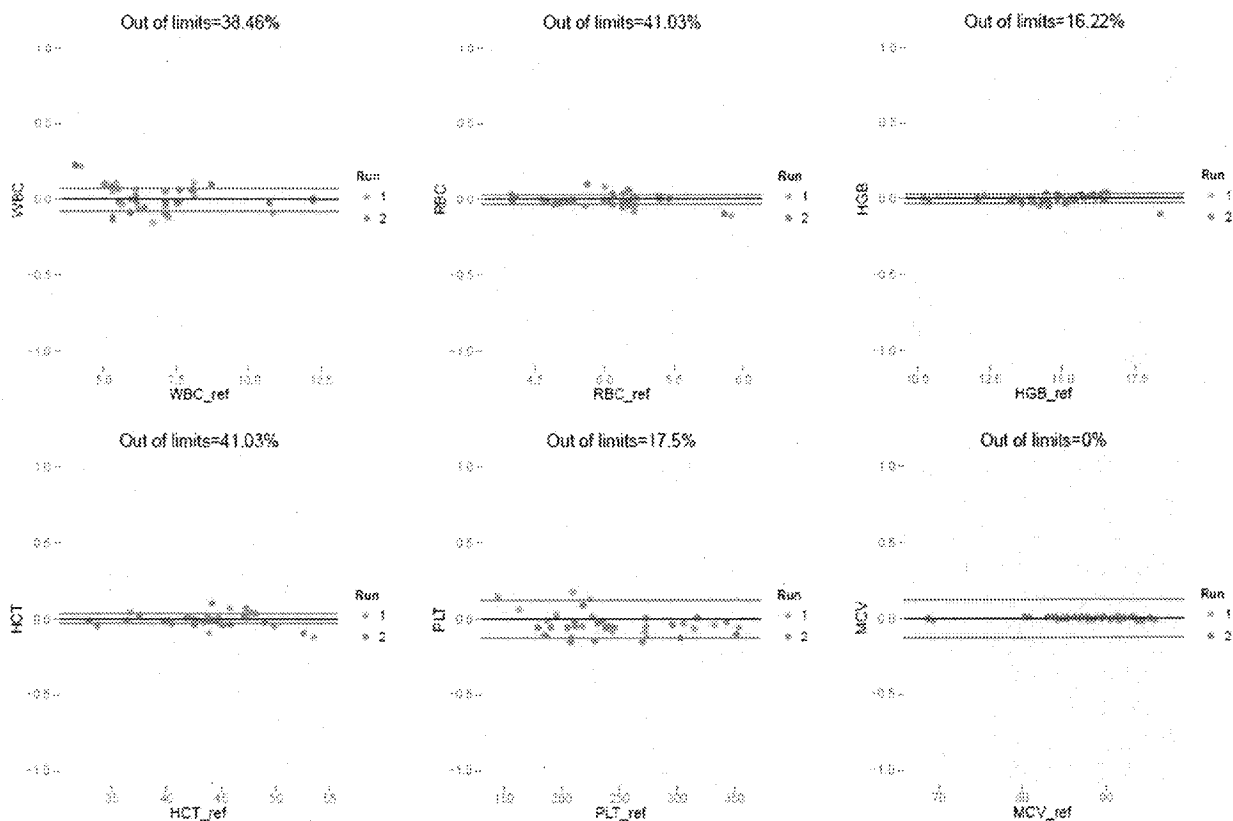


Figure 3a: Sample stability at 36h

theranos	Commercial System Verification Report	Verification of Drew 3 for Complete Blood Count	Rev:
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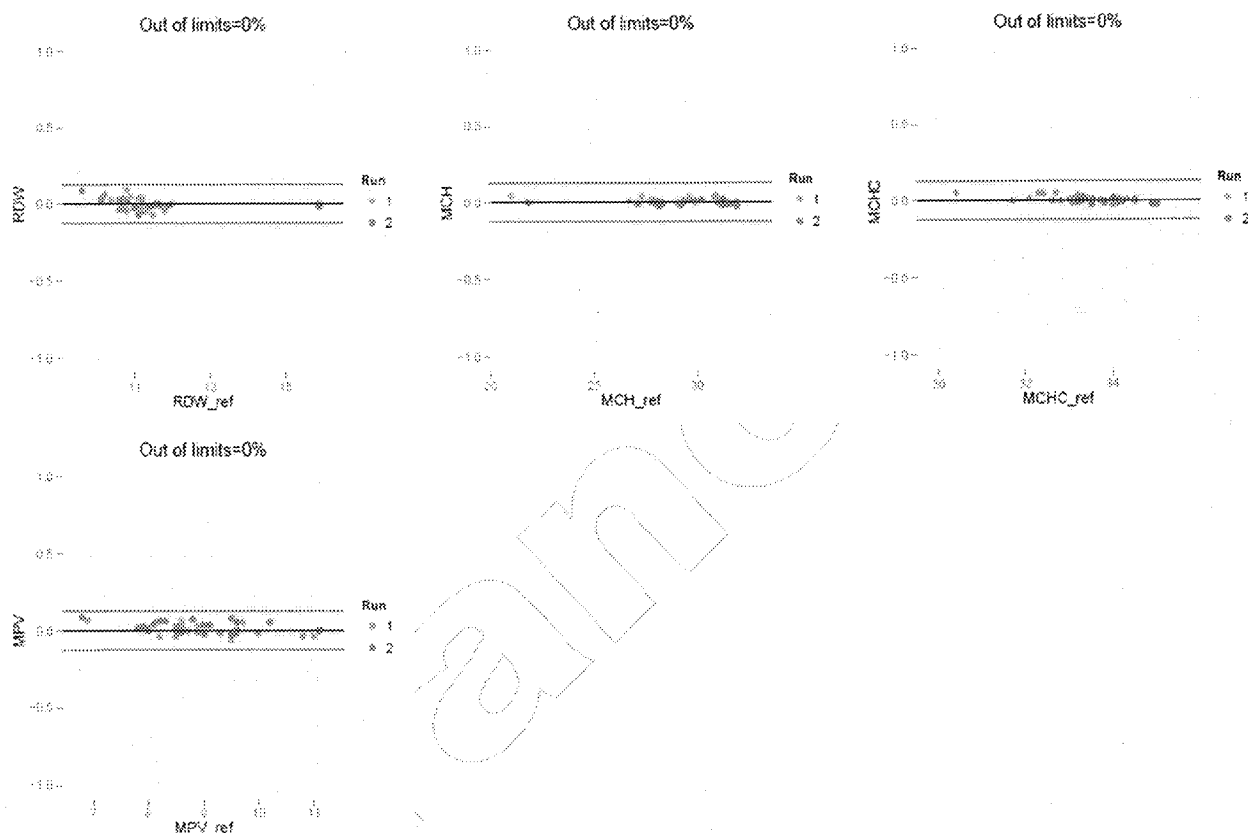


Figure 3b : Sample stability at 36h

theranos	Drew3 Summary	CBC Assay	Rev:
		CL RPT-14028	1
Description	Validation Report for Drew3 for CBC Assay		
Originator: Cindy Chung		Date: 11/12/2015	

Note to File

TO: Quality Department, Theranos
 FROM: Laboratory Director
 SUBJECT: Validation of CBC Assay
 DATE: November 5, 2015

Summary: Verification of CBC Assay

Theranos has verified the use of Drew Scientific Drew-3 hematology analyzer for Complete Blood Count (CBC) Assay. The Verification Report was prepared by Poornima Kolhar on August 30, 2014.

Specimen Type: Whole blood

Container: Theranos Sample Capillary Device and BD vacutainer

Anticoagulant: K2EDTA

Precision The closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. Precision was tested using whole blood from 4 donors, with 12 replicates of each. MCH and MCHC are calculated values; therefore, precision analysis is redundant and not relevant.

Measurand	Drew 510K	Calculated SD,r	Verification Value (VV)	Donor 1		Donor 2		Donor 3		Donor 4		Pass/Fail
	%CV			n = 12		n = 12		n = 12		n = 12		
				Value	SD	Value	SD	Value	SD	Value	SD	
		Verification Limit within run (SD,r or VV)										
WBC (10 ³ /ul)	2	0.16	-	7.14	0.07	4.97	0.10	4.65	0.08	7.36	0.12	Pass
RBC (10 ⁶ /ul)	1	0.05	-	4.94	0.03	4.68	0.03	4.87	0.04	4.62	0.05	Pass
HGB (d/dL)	0.6	0.09	-	15.78	0.08	13.99	0.07	14.93	0.07	14.48	0.08	Pass

theranos	Drew3 Summary	CBC Assay	Rev:
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Description	Validation Report for Drew3 for CBC Assay		
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HCT (%)	1	0.43	0.65	46.69	0.31	42.08	0.33	43.93	0.34	42.53	0.48	Pass
MCV (fL)	0.4	0.33	0.54	94.44	0.37	90.00	0.52	90.19	0.43	92.04	0.46	Pass
RDW (%)	3.3	0.44	-	10.94	0.32	10.88	0.30	10.33	0.31	11.10	0.30	Pass
PLT (10 ³ /ul)	3.6	11.06	-	178.67	9.20	213.58	4.36	282.92	9.51	281.08	7.42	Pass
MPV (fL)	1.2 (2.9)	0.09 (0.21)	0.14 (0.32)	8.77	0.14	8.53	0.17	8.16	0.12	7.75	0.18	Pass*

* MPV value and %CV from an independent precision test of 10 replicates also reported in the Drew3 manual and their corresponding SD and verification value are shown in parenthesis. Using these values, MPV passes precision verification.

Precision is within acceptable limits.

PASS

Accuracy Defined by CLSI as the closeness of agreement between a test result and an accepted reference value. The accuracy was determined by comparing the recoveries of 59 unique donors between Drew3 (510K approved) to Cell-Dyn Ruby (510K approved). The mean bias and its 95% confidence interval must be within the allowable % bias, which is defined as: Allowable % bias = total allowable error (TAE) limits stipulated by CLIA – 2 x CV_{precision}.

Measurand	Mean recovery	Mean Bias	95% CI Min	95% CI max	TAE (%)	Allowable bias (%)	Within Acceptable Limits?
WBC	103.60	3.6%	2.4%	4.9%	15	±13	Yes
RBC	99.41	-0.6%	-1.0%	-0.2%	6	±5	Yes
HGB	98.94	-1.1%	-1.4%	-0.7%	7	±6.4	Yes
HCT	102.23	2.2%	1.8%	2.7%	6	±5	Yes
PLT	93.09	-6.9%	-7.9%	-5.9%	25	±21.4	Yes
MCV	102.84	2.8%	2.6%	3.1%	5	±4.6	Yes
RDW	91.73	-8.3%	-9.5%	-7.1%	15	±11.7	Yes
MCH	99.53	-0.5%	-0.7%	-0.2%	9	±8	Yes
MCHC	96.79	-3.2%	-3.5%	-2.9%	10	±9	Yes
MPV	129.05	29.1%	27.1%	31.0%	15	±13.8	No

theranos	Drew3 Summary	CBC Assay	Rev:
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The mean bias and its 95% confidence interval (CI) is within the allowable % bias for all analytes, with the exception of MPV. Difference in MPV is due to a method difference and a reference range must be verified for MPV (see reference range summary).

PASS after MPV reference range verification.

Limit of Blank The highest value in a series of results on a sample that contains no analyte. Distilled water was run in 12 replicates to quantify limit of blank on Drew3. MCV, RDW, and MPV are cellular characteristics and HCT, MCH, and MCHC are calculated values; therefore a limit of blank is not relevant for these measurands.

Measurand	Limit of blank, With carryover	Acceptable Limit	Within acceptable Limit?
RBC ($10^6/\mu\text{L}$)	0	< 0.25	Pass
HGB (g/dL)	0	< 0.6	Pass
PLT ($10^3/\mu\text{L}$)	2	< 7	Pass
WBC ($10^3/\mu\text{L}$)	0.1	< 0.6	Pass

Sensitivity is within acceptable limit.

PASS

Linearity Ability of a quantitative analytical method to provide results that are directly proportional to the concentrations of an analyte in test samples, within a given measuring interval. MCV, RDW, and MPV are cellular characteristics and HCT, MCH, and MCHC are calculated values; therefore, linearity is not relevant for these measurands. Linearity is established, according to CLSI EP06-A, with an allowable non-linearity of <10%.

Measurand	R ²	# of Levels	510k Range	Verified range	510K Range Verified (Pass/Fail)
RBC($10^6/\mu\text{L}$)	0.9988	8	0.25-7.98	0.07- 7.37	Pass
HGB(g/dL)	0.9986	8	0.6 – 23.12	0.1- 20.6	Pass
PLT($10^3/\mu\text{L}$)	0.9977	10	7- 2806	28-2296	> 18 Pass*
WBC($10^3/\mu\text{L}$)	0.9968	10	0.6-117.6	0.1- 88.2	Pass

* Greater than 10% non-linearity detected at PLT level = 18 by Statis Pro. All PLT levels above 18 pass linearity.

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Linearity is within acceptable limits for the verified ranges in the table.

PASS

Reference Interval Verification Interval between and including two reference limits


Measurand	Proposed Reference Interval	% Outside range	Pass/Fail
WBC	2.9 – 11.6 $10^3/\mu\text{L}$	0%	Pass
RBC	4.7- 5.9 $10^6/\mu\text{L}$	0%	Pass
HGB	11.7-17.1 g/dL	0%	Pass
HCT	34- 53.1 %	8%	Pass
PLT	118- 422 $10^3/\mu\text{L}$	3.4%	Pass
MCV	77- 97.8 fL	8%	Pass
RDW	10.8-14.1 %	40.6%	Fail
MCH	24.4- 32.6 pg	3.4%	Pass
MCHC	28.9- 33.6 g/dL	0%	Pass
MPV	6.5- 13.5 fL	0%	Pass

Reference interval is within acceptable limit for all measurands except for RDW. A new reference interval or a bias correction has to be established for RDW.

I have reviewed all validation documents and supportive data and have found that the performance of the method is considered acceptable.

Laboratory Director
November 5, 2015

EXHIBIT 13

	Standard Operating Procedure	Document Number: CL SOP-15021 Revision: A
	CLIA Laboratory	Effective Date: 09/09/2013
SOP BD LSRFortessa		

BD LSRFortessa

Author(s):

Signature:	Date:
Name: Marilyn Nourse, Ph.D.	Title: Senior Scientist

Reviewer(s):

Signature:	Date:
Name: Daniel Young, Ph.D.	Title: Vice President

Approver(s):

Signature:	Date:
Name: Adam Rosendorff, M.D.	Title: Laboratory Director

The Laboratory Director or designee will review this procedure at least annually, including revisions.

Reviewed by:	Date:	Comments:

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BD LSRFortessa

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SOP BD LSRFortessa		

1. Purpose

- 1.1. The BD LSRFortessa is a commercially available flow cytometer capable of analyzing the fluorescence and scatter properties of suspensions of particles (including cells and beads).
- 1.2. This document describes the operation of the BD LSRFortessa for analyzing samples that have been prepared by Tecan 1 and Tecan 2 for complete blood count measurements (RBC Count, PLT Count, WBC Count, and WBC differential).

2. Scope

- 2.1. This procedure applies to all authorized CLIA Laboratory personnel using the BD LSRFortessa flow cytometer.

3. Definitions and Abbreviations

- 3.1. CS&T: cytometer setup and tracking
- 3.2. HTS: high throughput sampler
- 3.3. FFSS: FACS Flow Supply System

4. Responsibilities

- 4.1. It is the responsibility of the supervisors to ensure that all the personnel using the CELL-DYN Ruby analyzer are aware of all safety precautions.
- 4.2. It is the responsibility of all personnel to follow Universal/ Standard Precautions, this SOP and related SOPs reference below.

5. Materials and Equipment

- 5.1. BD LSRFortessa Flow Cytometer with High Throughput Sampler (HTS) and FACS Flow Supply System (FFSS) installed. BD LSRFortessa serial number = H64717700053
- 5.2. Cytometer Setup and Tracking (CS&T) Beads for which a valid baseline has been established on the BD LSRFortessa.
- 5.3. FACS Sheath with Surfactant, 20L cubitainer
- 5.4. FACS Sheath
- 5.5. FACS Clean
- 5.6. Coulter LH Series Cleanser
- 5.7. 0.5% Contrad in deionized water
- 5.8. Deionized water
- 5.9. Bleach

6. Quality control

- 6.1. Computer login:
 - 6.1.1. User ID: Administrator
 - 6.1.2. Password: theranos
- 6.2. BD FACS Diva software login:

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- 6.2.1. User ID: Administrator
- 6.2.2. Password: (blank)
- 6.3. Daily Setup:
 - 6.3.1. Take CS&T beads out of fridge (located below the bench to the right of the LSRFortessa)
 - 6.3.2. Turn BD LSRFortessa ("Fortessa") on (green button on the side facing the computer)
 - 6.3.2.1. Note: if you need to turn off the Fortessa, always wait at least 2 minutes before turning it back on
 - 6.3.3. Waste container:
 - 6.3.3.1. Note: do not screw the cap on until it is tight – make sure that it has some wiggle room so that it is effectively vented to atmospheric pressure.
 - 6.3.3.2. When the waste container is nearly full, remove the cap and place it upright (so the sensor does not get triggered).
 - 6.3.3.3. Pour out the waste into the sink (the waste already contains 10% bleach, and the samples we run are already fixed, so the biohazard has been neutralized twice). Run cold water for at least 1 minute to clear out the pipes from the bleach.
 - 6.3.3.4. Pour 1L of bleach into the bottom of the container (there is a line on the container) and replace it under the cytometer.
 - 6.3.4. Purge 2 sheath lines to rid them of any air bubbles.
 - 6.3.5. Check the FACS Sheath with surfactant cubitainer on the FFSS. If it is low (there will be a light indicating it has decreased to 1.5L) then replace the cubitainer with a new one.
 - 6.3.5.1. To change out the sheath, carefully remove the probes and place them in the cup on the side of the cart. Remove the sheath cube and set it aside. Place a new sheath cube on the cart and carefully insert the probes.
 - 6.3.5.2. Pour the remaining sheath fluid from the old cube into a 2L bottle for future use.
 - 6.3.6. Check the level of sheath in the plenum (reservoir) and make sure it is just to the bottom of the probes in the grey cap.
 - 6.3.7. Turn computer on if it is not already on.
 - 6.3.8. Open FACS Diva 7 software.
 - 6.3.8.1. User ID: Administrator
 - 6.3.8.2. Password: leave blank
 - 6.3.9. Put cytometer in Run mode (button on front panel).
 - 6.3.10. Go to HTS → Prime
 - 6.3.10.1. Look for bubbles in the two syringes
 - 6.3.11. Prime the HTS at least TWICE – more if there are bubbles in the syringes.
 - 6.3.12. Put the cytometer in Standby mode (button is on the machine itself).
- 6.4. Run the following procedure at the beginning of each day on which samples are to be analyzed.
- 6.5. In the FACSDiva software, go to Cytometer → CST

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
- 6.5.1. This opens the CST software within Diva.
- 6.5.2. Make sure Cytometer Configuration says "Theranos-2 HTS - CST SORP..."
- 6.5.3. Select "Check performance" from the drop-down menu
- 6.5.4. Make sure "Load tube manually" button is not checked
- 6.5.5. Make sure 96 well U bottom plate is selected
- 6.5.6. If you need to use a different type of 96-well plate (such as flat-bottom or V-bottom) you MUST change the type of plate that is specified. The probe enters the well at a distance that is calibrated to the plate type so you may damage it if the wrong type is selected.
- 6.5.7. Put 1 drop of well-mixed BD FACSDiva CS&T Research Beads and 150 uL of FACS Flow sheath fluid into well A1 of a clean 96-well U-bottom plate. Mix by pipetting.
 - 6.5.7.1. The CS&T Bead lot must already have a baseline associated with it. Valid bead lots will be available from the pull-down "Setup Control" menu.
- 6.5.8. Select the appropriate bead lot under "Setup Beads" in the "Setup Control" menu.
- 6.5.9. Put the plate on the HTS loader with the loaded well nearest the "A1" marking.
- 6.5.10. Put the cytometer in Run mode (button on the front of the cytometer)
- 6.5.11. Click "Run" () in the CS&T application
- 6.5.12. You should see events appear on all three dotplots that are displayed. These populations will move around as the software controls the PMT voltages and other settings.
- 6.5.13. When CST is finished, place cytometer in Standby mode.
- 6.5.14. Click View report
- 6.5.15. Verify that the QC passed
- 6.5.16. If it didn't pass, make a fresh dilution of CS&T beads and try again.
- 6.6. If CS&T still does not pass:
 - 6.6.1. Symptom: If you see dots on the Violet and Red plots, but not on the Blue plot, then the CST will not pass.
 - 6.6.1.1. Sometimes the CST fails because of a laser not being on or the wrong power. The error message that shows up in this case will probably say something about not being able to find the beads or that the event count is too low.
 - 6.6.1.2. If this is the case, turn off the Fortessa, WAIT TWO MINUTES, then turn it back on.
 - 6.6.1.3. If it still doesn't pass, run a 4x4 clean cycle with 5% Contrad in wells G9-G12 (see below). Repeat CST.
- 6.7. If you are still unable to solve the problem, check with a member of the cytometry team or call BD support (<http://www.bdbiosciences.com/services/techsupport/>). BD will ask for the serial number of the instrument, which is listed at the top of this document.

7. Procedure

- 7.1. Computer login:
 - 7.1.1. User ID: Administrator

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- 7.1.2. Password: theranos
- 7.2. BD FACS Diva software login:
- 7.2.1. User ID: Administrator
- 7.2.2. Password: (blank)
- 7.3. Analyzing a CBC plate:
- 7.3.1. First analyze the RBCPlt wells:
- 7.3.1.1. In the Browser window, click on the Clinical folder
- 7.3.1.2. Make a new experiment from a template:
- 7.3.1.3. Use the Experiment > New Experiment command to create a new experiment based on a saved template. Select the appropriate template and then click OK.
- 7.3.1.3.1. Template for RBC/PLT samples is called RBCPlt_Clinical
- 7.3.1.4. Re-name your experiment by right-clicking on the experiment name and selecting re-name. You can also do this by selecting the experiment and changing the name in the Inspector window 
- 7.3.1.4.1. Use the following naming format:
- 7.3.1.4.2. YYYYMMDD_assay type_plate # (from barcode scanner)
- 7.3.1.4.2.1. i.e. 20130909_RBCPlt_Clinical_plateRD0001
- 7.3.1.4.3. After typing the above information, keep the cursor in the box and use the barcode scanner to scan the plate barcode. It will automatically fill in the plate number.
- 7.3.1.4.4. Please note that the word "Clinical" (from the template) needs to be included in the experiment name.
- 7.3.1.5. Double click the 96-well U-bottom plate icon ( 96 Well - U bottom) under the experiment to open the plate window.
- 7.3.1.5.1. Note: please make sure the type of plate containing your samples is the same as the plate type specified.
- 7.3.1.6. If there are fewer than 24 samples on the plate, select the wells in the plate window that do not have sample and delete them according to the plate map (paper should accompany the plate).
- 7.3.1.7. Verify that "Standard Throughput" is selected in the upper-right corner of the Plate window
- 7.3.1.8. Verify the loader settings (change values if necessary):
- 7.3.1.8.1. Each well needs to have 50 uL of overage. For example, if you have 150 uL loaded in the well, the max sample volume should be 100 uL to leave 50 uL in the plate. The mixing volume should be  half the volume that is in each well.
- 7.3.1.8.2. Click on various wells in the plate window to verify RBC/PLT template loader settings:
- 7.3.1.8.2.1. Sample flow rate 1.0 uL/sec
- 7.3.1.8.2.2. Sample volume 100
- 7.3.1.8.2.3. Mixing volume 75

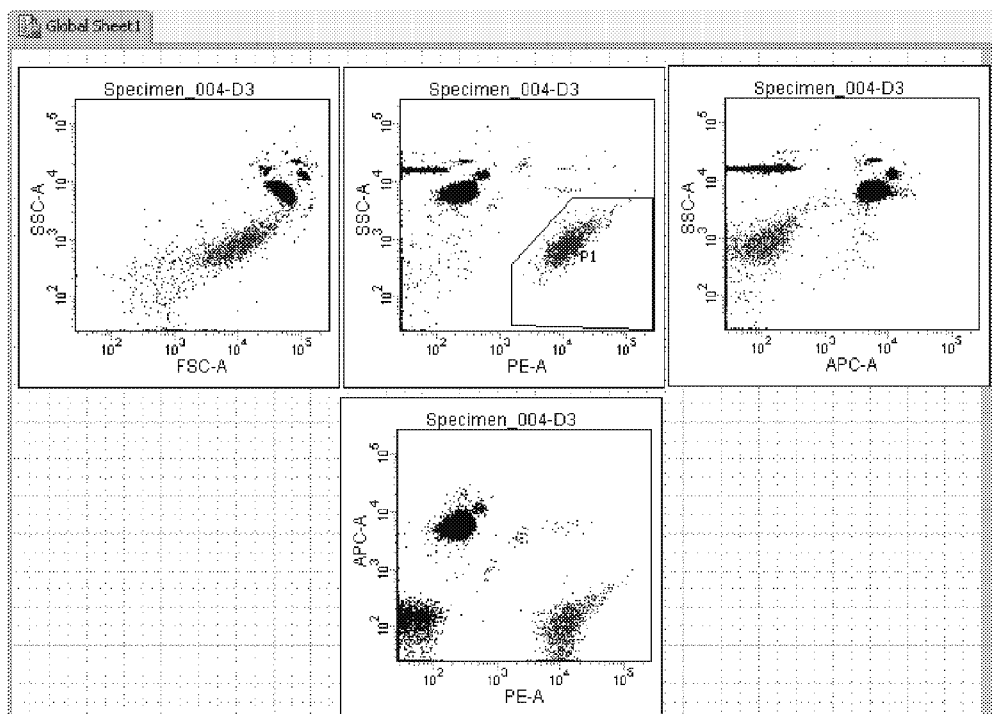
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- 7.3.1.8.2.4. Mixing speed 250
- 7.3.1.8.2.5. Number of mixes 5
- 7.3.1.8.2.6. Wash volume 800
- 7.3.1.9. Go to Experiment → Experiment Layout
 - 7.3.1.9.1. Click on the Acquisition tab
 - 7.3.1.9.2. Verify the number of events to record:
 - 7.3.1.9.2.1. For RBC/PLT samples, the number of events should be 1200 for all sample wells (this will be the number of platelets that is collected)
- 7.3.1.10. Verify the cytometer parameters (in the Cytometer window):
 - 7.3.1.10.1. For RBC/PLT assay:
 - 7.3.1.10.1.1. FSC-A
 - 7.3.1.10.1.2. SSC-A
 - 7.3.1.10.1.3. FITC-A
 - 7.3.1.10.1.4. PE-A
 - 7.3.1.10.1.5. APC-A
- 7.3.1.11. Verify the threshold (in the cytometer window)
- 7.3.1.12. For RBC/PLT assay:
 - 7.3.1.12.1. FSC threshold should be 200
- 7.3.1.13. Verify the loader settings by selecting a few wells in the Acquisition Dashboard window and make sure the settings are as described in section 7.3.1.8.2 above.
- 7.3.1.14. Remove the plate cover, if applicable.
- 7.3.1.15. In the Acquisition Dashboard window, make sure that the “stopping gate” is set to P1
- 7.3.1.16. Load your plate onto the HTS tray (make sure Well A1 is in the space marked A1 on the plate loader). Press the Run button on the cytometer.
- 7.3.1.17. Acquiring Data
 - 7.3.1.17.1. Select the first well of your wells to be acquired and click “Run Plate”.
 - 7.3.1.17.2. The cytometer will proceed to draw up the specified amount of sample and run it until the specified number of events has been acquired. The remaining sample will be discarded and the system will be flushed with the specified amount of sheath fluid. It will then move on to the next sample until it has completed the plate.
- 7.3.1.18. During acquisition, verify that the staining patterns look roughly correct:
- 7.3.1.19. RBCPlt:

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7.3.1.20.

7.3.1.21. If anything looks wrong, click "Pause" on the Acquisition Dashboard. The run will pause after the current well has completed. Then click "Stop Plate" and perform any remedial action deemed necessary, such as priming the flow cell, priming the HTS, or running a clean cycle (see troubleshooting section of this document for specific instructions). Then resume running the plate.

7.3.1.21.1. Run the next well by selecting the well and clicking "Run Well(s)" in the Acquisition Dashboard. If the problem is resolved, then select the next well and click "Run Plate".

7.3.1.21.2. If the problem is not resolved, call someone from the cytometry team and run a short clean

7.3.1.22. When acquisition is finished, place the LSRFortessa in Standby mode. It will not do this itself.

7.3.1.23. After the samples have been acquired, do a quick check to make sure the data looks roughly correct (see figures above)

7.3.1.24. Before running the WBC samples, Prime the HTS.

7.3.2. Analyzing WBC wells:

7.3.2.1. In the Browser window, click on the Clinical folder


7.3.2.2. Make a new experiment from a template:

7.3.2.3. Use the Experiment > New Experiment command to create a new experiment based on a saved template. Select the appropriate template and then click OK.

7.3.2.4. Template for WBC samples is called WBC_Clinical

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7.3.2.5. Re-name your experiment by right-clicking on the experiment name and selecting re-name. You can also do this by selecting the experiment and changing the name in the Inspector window 


7.3.2.5.1. Use the following naming format:

7.3.2.5.1.1. YYYYMMDD_assay type_plate # (from barcode scanner)

7.3.2.5.1.2. i.e. 20130909_WBC_Clinical_plateRD0001

7.3.2.5.1.3. After typing the above information, keep the cursor in the box and use the barcode scanner to scan the plate barcode. It will automatically fill in the plate number.

7.3.2.5.1.4. Please note that the word "Clinical" (from the template) needs to be included in the experiment name.


7.3.2.6. Double click the 96-well U-bottom plate icon ( 96 Well - U bottom) under the experiment to open the plate window.

7.3.2.6.1. Note: please make sure the type of plate containing your samples is the same as the plate type specified.

7.3.2.7. If there are fewer than 24 samples on the plate, select the wells in the plate window that do not have sample and delete them according to the plate map (paper should accompany the plate).

7.3.2.8. Verify that "Standard Throughput" is selected in the upper-right corner of the Plate window

7.3.2.9. Verify the loader settings (change values if necessary) – in the Plate Window:

7.3.2.9.1. Each well needs to have 50 uL of overage. For example, if you have 150 uL loaded in the well, the max sample volume should be 100 uL to leave 50 uL in the plate. The mixing volume should be  half the volume that is in each well.

7.3.2.9.2. Click on various wells in the plate map to verify WBC template loader settings:

7.3.2.9.2.1. Sample flow rate 1.0 uL/sec

7.3.2.9.2.2. Sample volume 135 uL

7.3.2.9.2.3. Mixing volume 100 uL

7.3.2.9.2.4. Mixing speed 180

7.3.2.9.2.5. Number of mixes 5

7.3.2.9.2.6. Wash volume 800

7.3.2.10. Go to Experiment → Experiment Layout

7.3.2.10.1. Click on the Acquisition tab

7.3.2.10.2. Verify the number of events to record:

7.3.2.10.2.1. For WBC samples, the number of events should be 15,000 for all sample wells.

7.3.2.10.3. To change multiple rows at the same time, click the first one, then hold the shift key and select the last one. Then change the value either using the list on the right panel or the pull-down menu at the top of the window.

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7.3.2.11. Verify the cytometer parameters (in the Cytometer window):

7.3.2.11.1. For WBC assay:

7.3.2.11.1.1. FSC-A

7.3.2.11.1.2. SSC-A

7.3.2.11.1.3. FITC-A

7.3.2.11.1.4. PE-A

7.3.2.11.1.5. PE-Cy5-A

7.3.2.11.1.6. APC-A

7.3.2.11.1.7. DRAQ5-A

7.3.2.11.1.8. Pacific Blue-A

7.3.2.12. Verify the threshold (in the Cytometer window)

7.3.2.12.1. For WBC assay:

7.3.2.12.1.1. FSC threshold should be 7,000

7.3.2.13. Verify the loader settings by selecting a few wells in the Acquisition Dashboard window and make sure the settings are as described in section 7.3.2.9.2 above.

7.3.2.14. In the Acquisition Dashboard, make sure that the "stopping gate" is set to P1

7.3.2.15. Press the Run button on the cytometer.

7.3.2.16. Acquiring Data


7.3.2.17. Select the first well of your wells to be acquired and click "Run Plate".

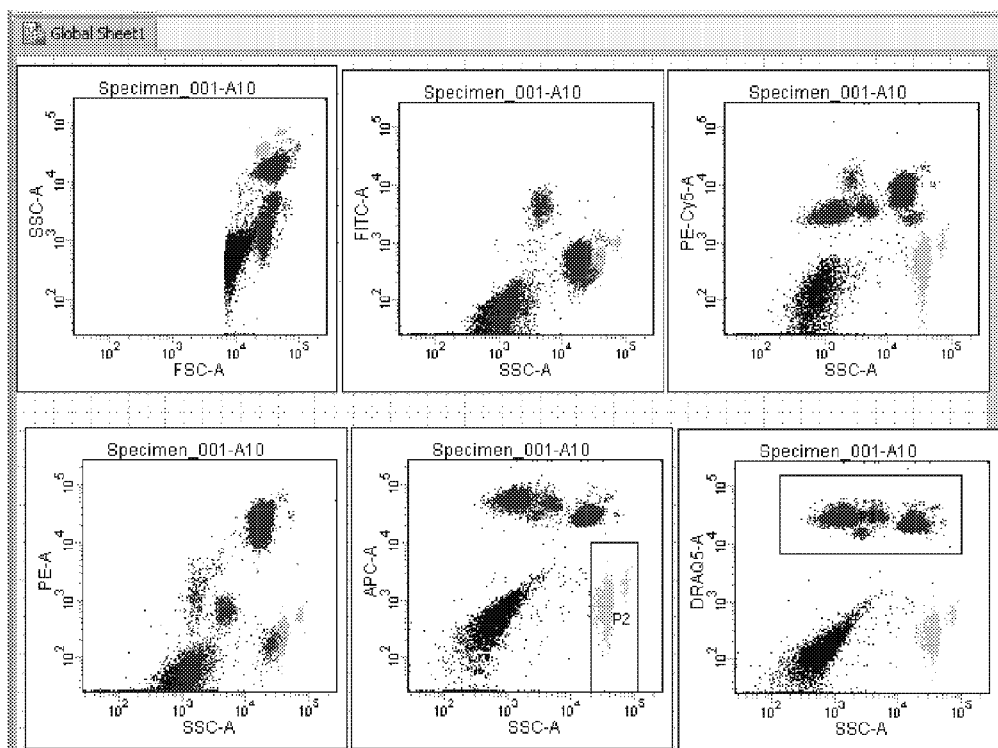
7.3.2.18. The cytometer will proceed to draw up the specified amount of sample and run it until the specified number of events has been acquired. The remaining sample will be discarded and the system will be flushed with the specified amount of sheath fluid. It will then move on to the next sample until it has completed the plate.

7.3.2.19. During acquisition, verify that the staining patterns look roughly correct:

7.3.2.20. WBC:

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7.3.2.21.

7.3.2.22. If anything looks wrong, click "Pause" on the Acquisition Dashboard. The run will pause after the current well has completed. Then click "Stop Plate" and perform any remedial action deemed necessary, such as priming the flow cell, priming the HTS, or running a clean cycle (see troubleshooting section of this document for specific instructions). Then resume running the plate.

7.3.2.22.1. Run the next well by selecting the well and clicking "Run Well(s)" in the Acquisition Dashboard. If the problem is resolved, then select the next well and click "Run Plate".

7.3.2.22.2. If the problem is not resolved, call someone from the cytometry team and run a short clean

7.3.2.23. When acquisition is finished, place the LSRFortessa in Standby mode. It will not do this itself.

7.3.2.24. After the samples have been acquired, do a quick check to make sure the data looks roughly correct (see figures above)

7.3.3. Cleaning [do this after every WBC run, any experiment with "dirty" samples, and at the end of every day]:

7.3.3.1. Prepare the following wells in a 96-well U-bottom plate (you can use your experiment plate if these wells are available):

7.3.3.1.1. E9-E12: 250 uL FACS Clean (stabilized 10% Bleach; you can also use freshly prepared 10% bleach)

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- 7.3.3.1.2. F9-F12: 250 uL Coulter LH Series Cleaner (blue liquid; contains proteolytic enzymes)
- 7.3.3.1.3. G9-G12: 250 uL 0.5% Contrad (detergent) [use 5% Contrad if you are trying to clear out a clog]
- 7.3.3.1.4. H9-H12: 250 uL deionized/Milli-Q H₂O
- 7.3.3.2. Put the plate on the HTS with well A1 in the corner marked "A1"
- 7.3.3.3. In the Browser, go to the folder called "CLEANING" and make a new blank experiment.
- 7.3.3.4. Go to HTS → Clean
- 7.3.3.5. Select "Clean4x4" from the list of templates.
- 7.3.3.6. Put the cytometer in Run mode and say "yes" or "OK" to all the dialog boxes that pop up. Clean cycle will begin.
- 7.3.3.7. Clean cycle will take about 20 minutes. Make sure to come back as soon as the clean is done because it will stay in Run mode, which drains the sheath fluid unnecessarily.
- 7.3.4. When the clean cycle is done, put the cytometer in Standby mode. If it is the end of the day, turn the Fortessa off (green button on the right side).

8. Troubleshooting

- 8.1. If the cell scattergrams look incorrect during acquisition, pause the acquisition as described in section 7 above and take the following steps:
 - 8.1.1. Check the fluidics
 - 8.1.1.1. Make sure the sheath container (box) is not low (1.5L light blinking) or out (alarm)
 - 8.1.1.2. If it is low, change to a new box of sheath and write "partial" on the old box. Prime the HTS a few times and check the lines for air to make sure everything is ok.
 - 8.1.1.3. Check the plenum (pressurized sheath reservoir next to the HTS) and make sure that the level of sheath is correct. It should be just above the bottom of the metal probe on the grey cap.
 - 8.1.1.3.1. If it is low, unscrew the metal cap to release the pressure.
 - 8.1.1.3.2. At this point, the pump should activate and pump some sheath from the box up to the probes.
 - 8.1.1.3.3. During a gap between pumps, use a twisted kimwipe to dry out the probe that is encased in a black cylinder.
 - 8.1.1.3.4. Screw the cap back on and make sure that the pump continues to fill (in run mode).
 - 8.1.1.4. Prime flow cell (button on the front of cytometer) and then prime HTS.

9. References

- 9.1. These can all be found at J:\Experiment Log\E0900 - E0999\E0959\Fortessa_User_Guides

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- 9.1.1. BD HTS User's Guide.pdf
- 9.1.2. CS&T Application Guide.pdf
- 9.1.3. 23-11093-00_LSRFortessa_ug.pdf
- 9.1.4. BD FACSDiva Software Reference Manual.pdf

REVISION HISTORY			
Revision Level	Effective Date	Initiator	ECO Number
A	12/2/2013	Adam Rosendorff	
Section Number	Description and Justification of Changes		

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EXHIBIT 14

	Standard Operating Procedure	Document Number: CL SOP-15018 Revision: B
	CLIA Laboratory	Effective Date: 08/17/2015
CBC: Tecan 1, Tecan 2, Drew, Fortessa, and Canto		

Author(s):

Signature:	Date:
Name: Kim Tran	Title: CLA

Reviewer(s):

Signature:	Date:
Name: Nishit Doshi, Ph.D.	Title: Manager, Product Development

Signature:	Date:
Name: Gurbir Sidhu	Title: General Supervisor

Approver(s):

Signature:	Date:
Name:	Title: Laboratory Director

The Laboratory Director or designee will review this procedure at least annually, including revisions.

Reviewed by:	Date:	Comments:

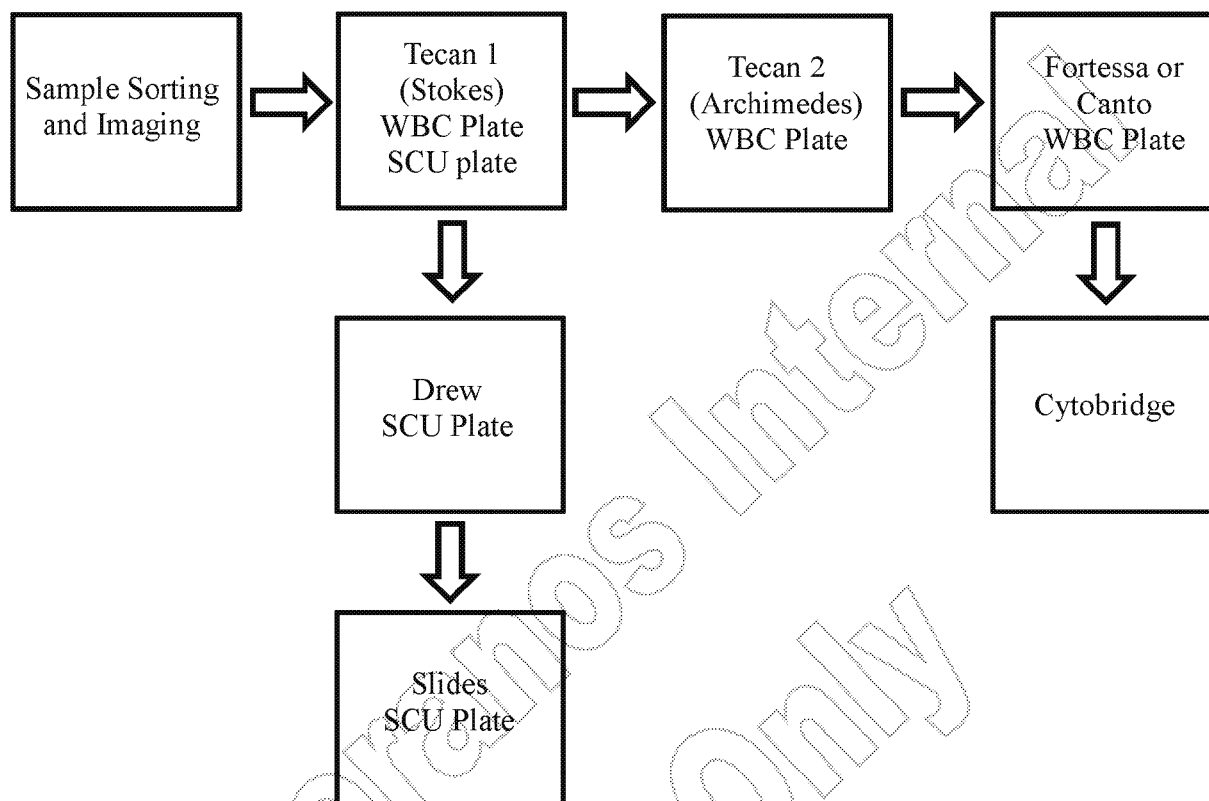
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CBC: Tecan 1, Tecan 2, Drew, Fortessa, and Canto		

CBC WORKFLOW



theranos	Standard Operating Procedure	Document Number: CL SOP-15018 Revision: B
	CLIA Laboratory	Effective Date: 08/17/2015
CBC: Tecan 1, Tecan 2, Drew, Fortessa, and Canto		

I. Purpose

Tecan 1, Tecan 2, Drew, Fortessa or Canto will be used to perform complete blood count (CBC) with differential on Theranos blood samples (Capillary Tube and Nanotainer).

II. Scope

This SOP outlines the workflow and operations on Tecan 1, Tecan 2, Drew3, Fortessa and Canto in terms of processing CTN Theranos blood samples.

III. Definition and Abbreviations

- a. LiHa: Liquid Handling – this represents one of the arms on the Tecan machine.
- b. The **SCU** (Sample Collection Unit) consists of the nanotainers, its holder, and the samples that are housed within them.
- c. CBC: Complete blood count
- d. WBC: White blood cell
- e. CS&T: Cytometer setup and tracking
- f. HTS: High throughput sampler
- g. Tecan 1: Liquid handling machine “Stokes”
- h. Tecan 1: Liquid handling machine “Archimedes”
- i. PBS: phosphate buffer saline
- j. FACS: fluorescence-activated cell sorting
- k. DI: deionized
- l. CTN: Capillary Tube and Nanotainer
- m. VV: Volume Verification

IV. Responsibilities

- a. **Licensed CLIA Personnel** are responsible for utilizing all machines in this SOP in day-to-day lab operations and for maintaining data integrity in the system.
- b. The **Theranos Laboratory Director** is responsible for maintaining data that can only be accessed by lab admin users such as reference ranges, CPT to LOINC code mapping, and user accounts.
- c. The **Theranos IT Support** team is responsible for maintaining system infrastructure and ensuring the automation application is secure and accessible at all times.

V. Equipment and Reagents

- a. Tecan 1 “Stokes”
 1. 1xPBS
 2. 2% Contrad
 3. 10% Bleach
 4. Low volume VV dye

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5. 96-well flat bottom plates
- b. Tecan 2 "Archimedes"
 1. Archimedes dailyVVC dye
 2. 125 uL Tecan tips
 3. 96-well flat bottom plates
- c. Drew3 machines (Drew3 #2 and Drew3 #3)
 1. Daily QC controls (Low, Normal, High)
 2. Drew3 Reagent Packs
- d. Bioshake
- e. Fortessa
 1. FACS sheath with surfactant
 2. 10% bleach
 3. FACS clean
 4. Coulter Clenz
 5. 0.5% contrad
 6. DI water
 7. FACS rinse
- f. Canto
 1. FACS sheath with surfactant
 2. 10% bleach
 3. FACS clean
 4. Coulter Clenz
 5. 0.5% contrad
 6. DI water
 7. BD shutdown solution

VI. Instrument Daily QC and Maintenance Procedures

- a. Tecan 1 "Stokes" Daily VV and Shutdown Procedure
 1. Turn on Tecan 1, the computer and scanner.
 2. Perform the daily pre-QC tasks
 - a. Complete all checklist duties
 - b. Open Evoware
 - c. Click "Edit existing script"
 - d. Click any of the script files and select "OK".
 - e. Click "Initialization"
 3. Open up Tecan 1 app and log in with your LIS username and password.
 4. Perform hourly flush by clicking "Execute Script"
 5. Daily VV
 - a. In the upper right-hand corner click "QC"
 - b. Then "Daily Tecan QC -> Daily Tecan QC CBC"


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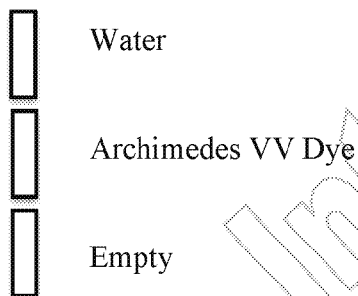
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- c. Follow the prompts on the screen (remember to use two aliquots of low volume dye, mix well and spin down in microcentrifuge)
 - d. Once the daily VV is complete, take the 96-well plate to the M5 plate reader and use the "Tecan Daily QC_M5 template.pda"
 - i. Open SoftMax Pro
 - ii. Select File -> Open.
 - iii. Navigate to N:\TecanQC and select "Tecan Daily QC_M5 template.pda". Click open.
 - iv. Load QC plate with A1 corner in the top left corner and click "Read".
 - e. Export the template into a new folder in the TecanQC folder on the N drive. Name the folder in this format "YYYYMMDD". Name the exported file as "StokesQC".
 - f. Run Rscript "TecanDailyQC_V1" on M5 computer desktop. "All Nozzles Passed" will display across from Stokes if VV passed.
 6. If daily QC does not pass, perform an hourly flush, make sure the nozzles are tight and check the syringes for any bubbles.
 7. Repeat the daily VV and name the new VV file as "StokesQC1". Please refer to **CL SOP 15019** for further information and troubleshooting.
 8. At the end of the day, follow the shutdown procedure on the daily checklist.
- b. Tecan 2 "Archimedes" Daily VV and Shutdown Procedure
1. Turn on Tecan 2 and the computer.
 2. Open Evoware
 - a. Login: admin, password: tecanadmin1
 - b. Click 'edit existing script'
 - c. Under history select "QC_TRACKtips_forprod" and select "OK".
 - d. Click 'initialize' and wait for machine to finish
 - e. Replace 125 uL tecan tips with a new box if necessary
 - i. If you replace a box before prompted by the software you must update the script for the starting tip location.
 - ii. On the desktop there is a shortcut folder called "scripts_shortcut".
 - iii. Inside the folder, open "DiTi_middle_2.txt". The first number is the starting column and the second number is the starting row. If you are putting in a new box then it should be "1,1". Remember to save the file.
 3. Run daily VV
 - a. Make sure the heat block is on and at 37°C
 - b. Make sure the top trough is at least half-way full with DI water
 - c. Add the Archimedes daily VV dye to middle trough
 - i. Daily VV dye is only good for one-time use. Discard after opening.

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CBC: Tecan 1, Tecan 2, Drew, Fortessa, and Canto		



- d. a 96-well flat bottom plate where it is labeled 'CBC plate'
 - e. Click 'run' and select "OK".
 - f. Once the daily QC is complete, take the 96-well plate to the M5 plate reader and use the "Tecan Daily QC_M5 template.pda"
 - i. Open SoftMax Pro
 - ii. Select File -> Open.
 - iii. Navigate to N:\TecanQC and select "Tecan Daily QC_M5 template.pda". Click open.
 - iv. Load QC plate with A1 corner in the top left corner and click "Read".
 - g. Export the template into a new folder in the TecanQC folder on the N drive. Name the folder in this format "YYYYMMDD". Name the exported file as "Archimedes".
 - h. Run R-script "TecanDailyQC_V1" on M5 computer desktop. "All Nozzles Passed for MMDDYYYY" will display across from Archimedes if VV passed.
4. If daily VV does not pass open a new VV dye, repeat the above process and name the new QC file as "ArchimedesQC1". Please refer to **CL SOP 15019** for further information and troubleshooting.
 5. At the end of the day follow the shutdown procedure on the daily checklist.
- c. Drew Daily QC and Shutdown Procedure
1. Remove the daily QC reagents from the 4°C fridge and allow to come to room temperature (about 15 minutes)

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- a. Drew controls are good for 1 week after opening. Label each tube with the open and expiration date and initials.
- b. Each lot of Drew QC controls is only good for three months. Once a new lot is received, it is necessary to enter in the new upper and lower limits. Please contact your supervisor before doing so and refer to CL QOP 00013 for general lab QC instruction and/or QC datasheet and Drew handbook for detailed instructions.
2. Turn on instrument and press “OK” to go the next screen
3. Check the reagents and replace with a new pack if necessary.
 - a. Open a new pack and transfer probes to appropriate bottles.
 - b. Go to “Maintenance” from the main menu and then select “Reagent Pack”
 - c. Enter in the lot number, expiration date and code from the side of the reagent pack. You may use the hand scanner to scan in the code.
 - d. Press “Change reagent pack” and click “Yes” when prompted about saving modifications.
 - e. Prime three times and press “Exit” to return to the main menu
 - f. If you replace a reagent pack in the middle of the day, always re-run the daily QC for the 3 controls.
4. Press the “START UP” icon on the screen to start fluidics and complete the background.
 - a. If the background fails, repeat the start-up cycle.



5. Press “Run Sample” when background is complete.
6. Click “Q.C” and select the appropriate QC lot and level (low, normal, or high).

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7. Make sure to mix the QC controls by inverting at least 10 times.
 8. Uncap the controls and completely submerge the probe in the tube. Click the button directly behind the probe.
 9. When the QC is done for that tube and there are no flags, press "Accept QC", then select "OK" and proceed with the next QC level tube. Repeat 6 – 8 until all 3 levels have passed.
 - a. If QC fails, please refer to CL QOP 00013 for general lab guidelines and CL SOP-06041 for detailed instructions.
 10. Shutdown Procedure
 - a. Change the reagent pack if necessary
 - b. Run 50% bleach after all samples are run.
 - c. Exit to the main menu and select "Maintenance" and then "Cleaning"
 - d. Once the cleaning procedure is complete, exit to the main menu and select "Shut Down"
 - e. Empty the waste if necessary
 - f. Wipe down instrument
 11. For Drew3 maintenance and troubleshooting see "Drew3 Maintenance and Troubleshooting guide"
 - d. Fortessa/Canto Daily QC and Shutdown Procedure
 1. Refer to *CL SOP-15021 SOP BD LSRFortessa*
 2. Refer to *CL SOP-15049 SOP BD FACS Canto-II*
- VII. Processing Patient Samples
- a. Receive and Sorting
 1. Spinning
 - a. After samples are received by the Accessioning Team, spin all EDTA (purple) CTNS at 1200 rcf for 5 minutes
 2. Sorting
 - a. Place CTNs on the white tray, open the sorting app (IntellisortProd.app) and follow the on screen instructions.
 - b. Login with your LIS username and password
 3. Reviewing Images
 - a. When a SCU plate is full, review the images for hemolysis, clots and leaks.
 - i. If a sample is hemolyzed and it is aliquoted from a vacutainer ask for a new aliquot to confirm.
 - ii. If a sample is clotted on both sides, reject the sample, check for other tests and alert the appropriate teams.

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- iii. If the sample is a shortfill (less than 60 uL of whole blood), but greater than 40 uL, run the sample, leave a note in LIS and request a slide review.
 - iv. If the sample cannot be ran on the left side but right side is okay to run, move samples to be ran on the right side on to a separate plate.
 - b. You MUST contact a CLS and or Supervisor about all the problem CTNs and leave notes in LIS for their records.
- 4. Add CTNs to trays app
 - a. If you need to add or remove CTNs from a specific SCU tray, use the “Add to tray” app.
 - b. Login with your LIS username and password.
- b. Aliquoting Samples and Running WBC Plates (CBC Differential)
 - 1. Aliquoting blood on Stokes
 - a. Spin down a WBC plate at 500 rcf for 2 min.
 - b. Prepare the WBC lyse/FIX buffer
 - i. Get an aliquot of FIX and a new tube of WBC lyse from the 4°C fridge
 - ii. Spin down the FIX aliquot for 1 min at 1800 rpm
 - iii. Add 808 uL of FIX into the WBC lyse buffer and mix
 - iv. Fill out the label on the tube for the addition of FIX, date made (DOM) and date of expiration (DOE). The WBC lyse/FIX is good for 2 days after it is mixed.
 - v. Scan in the 1D barcode from the WBC lyse and the 2D barcode into the CBC reagent spreadsheet (N drive -> Cyto -> Reagents -> Clinical)
 - c. Open the “Tecan1 app” on the desktop. Login with your LIS credentials.
 - d. If it has been more than 1 hour before Stokes was last used, perform an hourly flush.
 - e. Click “Next” on the screen and follow the prompts. Make sure to select the prompt to aliquot from either the left side or right side.
 - f. Make sure the bioshake on Stokes is working, it should shake 4 times for 15 seconds each.
 - g. Print out the SCU plate map through the “Whiteboard App” by using your credentials
 - i. Click on the “pending tests” tab and search for the SCU tray number
 - ii. Verify that the plate map matches the map on Stokes
 - h. Once Stokes is done aliquoting, carefully remove the WBC plate from Stokes, cover it with an adhesive seal and transfer it to Archimedes.
 - i. Remove the SCU tray, recap all of the CTNs and take them to Drew.

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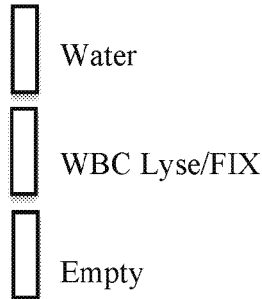
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2. Lyse and fix of samples on Archimedes

- a. Insert a 25 mL tecan trough into the middle 100 mL trough and pour in 20mL of the WBC lyse/FIX.



- b. Open up the following script “Drew_WBC”
- c. Make sure the door is down, click “Run” in Evoware and follow the prompts on the screen.
- i. The first prompt will ask how many loops you want to run. One loop equals one column on the WBC plate. Twenty-four samples is three loops, 16 samples is two loops, and 8 sample is one loop.
- d. After the script is completed, take the WBC plate to either Fortessa or Canto.

3. Running WBC plates on Fortessa or Canto

a. Fortessa

- i. During the last heat block incubation on Archimedes perform 1 HTS prime on Fortessa

- a. Press the Run button on the front of the cytometer, go to the “HTS” menu and click “Prime”
- b. Refer to *CL SOP-15021 SOP BD LSRFortessa* section 7.3 for detailed instruction on running patient samples and “Clean” plate.

b. Canto

- i. During the last heat block incubation on Archimedes purge the bubble filters, degas the flow cell and prime the HTS
- a. Go to the Cytometer menu -> Cleaning Modes -> Bubble Filter Purge and Degas Flow Cell
- b. HTS menu -> Prime
- c. Refer to *CL SOP-15049 SOP BD FACS Canto II* section 8 for detailed instruction on running patient samples and section 9 for “System and HTS Clean”.

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c. Running CTNs on Drew and Making Slides

1. Running samples on Drew

- Open "DrewBridge" app on Drew computer desktop and login with your LIS username and password.
- Insert a CTN into bioshake and click "BioShake Automated Shake.bat" on the Drew computer desktop. Allow CTN to shake for 1 min.
 - The bioshake will shake four times at 1800 rpm and 15 second intervals
 - Click the following scripts to lock (Lock BioShake.bat) or unlock (Unlock BioShake_Copy.bat) the bioshake. All scripts are located on the desktop.
- From main page on Drew analyzer, select "Run Samples".
- Immediately after bioshaking is done, use barcode scanner and scan in QR code on bottom of CTN. Remove the CTN cap from the left side, hold the CTN so the probe is completely submerged in the blood and press the toggle button behind the probe.
 - The probe will remove 10 uL of blood.
 - The light on the device will turn from green to red indicating that the device is busy.
- Results will show up after 1 minute, review to see if a re-run is required.
- When all samples are ran, click "Pause" in DrewBridge app and then click "Upload". Press "OK" when prompted.

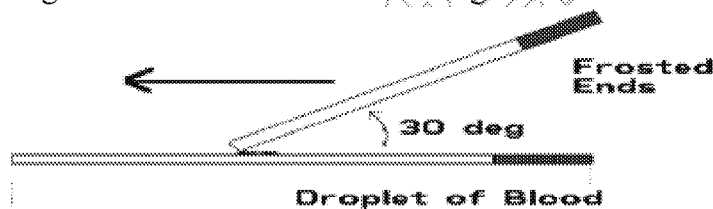
2. Drew re-run criteria:

	Rerun on Drew if any of the below is true:
WBC	$\leq 1.5 \times 10^3/\text{ul}$ or $> 15.0 \times 10^3/\text{ul}$
Plt	$< 100.0 \times 10^3/\text{ul}$ or $> 600.0 \times 10^3/\text{ul}$
RBC	$< 2.0 \times 10^6/\text{ul}$ or $> 7.0 \times 10^3/\text{ul}$
HGB	$< 7 \text{ g/dl}$ and $> 19 \text{ g/dl}$
HCT	$< 28\%$ and $> 50\%$
MCV	< 65 and > 100
	RBC, HGB, and MCHC are simultaneously flagged


- Make sure to notify a CLS and or supervisor in regards to any re-run information (CTN number and reason for re-run)

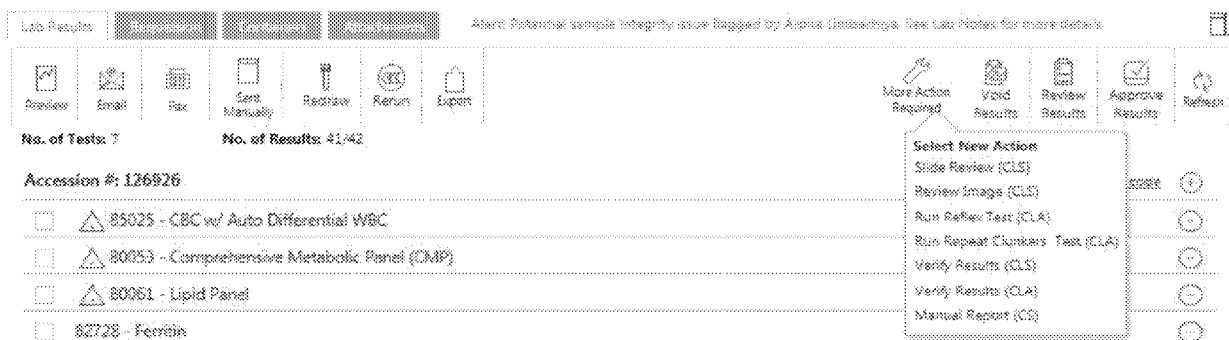
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- b. When all samples are ran, click “Pause” in DrewBridge app. Select the rerun result to upload by clicking the downwards arrow next to the sample and then click “Upload”. Press “OK” when prompted.
3. Making Blood Smears:
 - a. Place CTN in bioshake and shake at 1800 rpm for 15sec to 1 minute (depends on how long slides were sitting without agitation).
 - b. Pipet 4 uL of blood one third of the way up from the frosted end of the slide.
 - c. With the thumb and forefinger of your dominant hand, hold the end of a second slide against the surface of the first slide at an angle of 30-45 degrees, and draw it back to contact the drop of blood. Allow the blood to spread and form the angle between the two slides. See figure below:



- d. Push the spreader slide at a moderate speed forward until all the blood has been spread into a moderately thin film.
 - e. The thickness of the film can be adjusted by changing the angle of the spreader slide or the speed of spreading.
 - f. The film should have a smooth, even appearance and be free from ridges, waves, or holes.
 - g. Allow the slides to air dry.
 - h. Refer to CL SOP XXXXX for detailed descriptions on Blood Smear requirements.
- d. Cytobridging Data and Requesting Slide Reviews
1. Requesting Slide Reviews
 - a. After the WBC plate is gated, you may need to request slide reviews. They will provide a list of slide reviews and reasons for requesting.
 - b. Log into LIS and check the slide request from to verify if a differential was ordered. If the test is only CBC with no diff then a slide request is not needed.
 - c. Go to the patient's LIS record and select “More action Required” -> Slide Review (CLS).

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The screenshot shows the 'Lab Results' interface with tabs for 'Test Results', 'Test Results', and 'Test Results'. A message at the top states: 'Alert! Potential sample integrity issue flagged by Alpha Limbocyte. See Lab Notes for more details.' Below this are icons for 'Review', 'Email', 'Fax', 'Send Manually', 'Refresh', 'Rerun', and 'Export'. A summary bar shows 'No. of Tests: 7' and 'No. of Results: 41/42'. The 'Accession #' is 126926. A list of tests is shown with checkboxes and status icons: 85025 - CBC w/ Auto Differential WBC, 80053 - Comprehensive Metabolic Panel (CMP), 80061 - Lipid Panel, and 82728 - Ferritin. A 'More Action' dropdown menu is open, showing options: 'Slide Review (CLS)', 'Review Image (CLS)', 'Run Reflex Test (CLA)', 'Run Repeat Clunkers Test (CLA)', 'Verify Results (CLS)', 'Verify Results (CLA)', and 'Manual Report (CS)'.

- d. Select "Slide Review (CLS)"
 - e. Select a reason for the slide review in the "Reason for Review" drop down menu.
 - i. If you cannot find the criteria to match just put "other miscellaneous unusual populations"
 - f. Select CBC with Auto Differential WBC
 - g. Write the reason for the slide review in the "Description" box and do not select an assignee. Click confirm.
 - h. Notify a CLS and/or supervisor about the slide review. Fill out the slide request form and leave the slide in the pick area.
2. Cytobridging Data
- a. The cytobridge app is located on the computer (WS1170PA) near the printer in the CBC area.
 - b. Log into the app with your LIS username and password.
 - c. Enter the SCU plate number, make sure all of the plate information matches and click "next".
 - d. It may take a few minutes for the data to show up on the next screen. Scroll through the results and make sure there are no "NA" values. If there are "NA" values check in LIS to see if a CBC with differential was ordered. If a differential was not ordered, this patient will have NA values. Sometimes, we will get NA for only one values, such as basophils or eosinophils. Generally, this means that patient had zero for that cell type. It is important to always check with the gater to verify this and enter a note into LIS.
 - e. Click the "Submit" button at the bottom of the page **ONCE**. Clicking it more than one time will result in duplicate results in LIS.
 - f. After the upload is complete make a note on the CBC plate map that it was Cytobridged.

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VIII. Revision History

REVISION HISTORY			
Revision Level	Effective Date	Initiator	DCO Number
A	06/05/2015	Rachel Ochoa	CL DCO-00089
B	08/17/2015	K. Tran	CL DCO-00095
Section Number	Description and Justification of Changes		
All	Initial Release		
All	Revise to current practice		

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